

Applying Systems Engineering Methods to Develop a Manufacturable OME Solution

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I. Abstract

This report presents the development of a manufacturable warhead solution for a drone-delivered explosive device, designed to neutralise a hostile communications centre in an urban environment. The objective was to deliver a controlled explosive effect to a second-floor room from over 100 metres, while minimising collateral damage. Working within a structured systems engineering process, the team applied tools such as Quality Function Deployment (QFD), Function Means Analysis, Process Failure Mode and Effects Analysis (PFMEA) and Process Control Planning.

The manufacturing leads key focus was placed on evaluating production feasibility, identifying process risks and ensuring regulatory compliance. PE-8 extrusion was selected as the most suitable filling method, supported by detailed process mapping and risk mitigation aligned with the Manufacture and Storage of Explosives Regulations 2005 (MSER). Critical process steps and controls were identified to support repeatable, safe manufacture and waste disposal was addressed using approved methods for energetic residues.

The report outlines how manufacturing considerations influenced design decisions and demonstrates how risk-informed process planning supported safe system delivery from concept to disposal.

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1. Introduction

This report outlines the use of systems engineering tools to develop a manufacturable solution for a specified ordnance requirement. The report is written from the perspective of the lead manufacturing engineer and focuses on how manufacturing constraints, risks and process controls were used to influence and support the design.

The project brief required the design of an explosive device capable of neutralising a hostile communications centre located in a second-floor room of an office building. The system had to be accurately delivered from at least 100 metres away and designed to limit collateral damage to surrounding rooms. A stretch objective included the potential to disorient or immobilise occupants rather than eliminate them.

The team followed a structured design process using a defined toolset. This included requirement capture, stakeholder engagement, functional decomposition, concept generation and selection, risk assessment and process planning. The manufacturing role contributed to design feasibility assessment, process development and regulatory compliance, with particular focus on the warhead fill and integration process.

The report details requirement development, the rationale for design choices, manufacturing process planning and control measures to ensure product safety

and repeatability. It concludes with a summary of waste handling during manufacture and responses to technical feedback from the design review panel.

2. Key Customer Requirements & Manufacturing impacts

2.1. Requirement Development Overview

Requirements were developed in two stages. The first stage extracted explicit needs from the customer's brief, defining baseline operational performance and compliance parameters. These included minimum range, effect containment and the use of explosive means.

To refine this, a stakeholder mapping exercise was conducted (Figure 1) identifying all relevant actors across the system lifecycle. A Gemba visit [1] was then carried out at Salisbury Plain, with the full development team, two stakeholders and five end users. The visit included live demonstrations of current urban munitions systems (FGM-148 Javelin and M141 SMAW-D).

Observations highlighted that while these systems met performance goals, they exceeded the necessary effect and caused significant collateral damage. Feedback from the session informed additional requirements

around precision, safety, ease of manufacture and repeatability. These designer-derived requirements complemented the original customer brief.

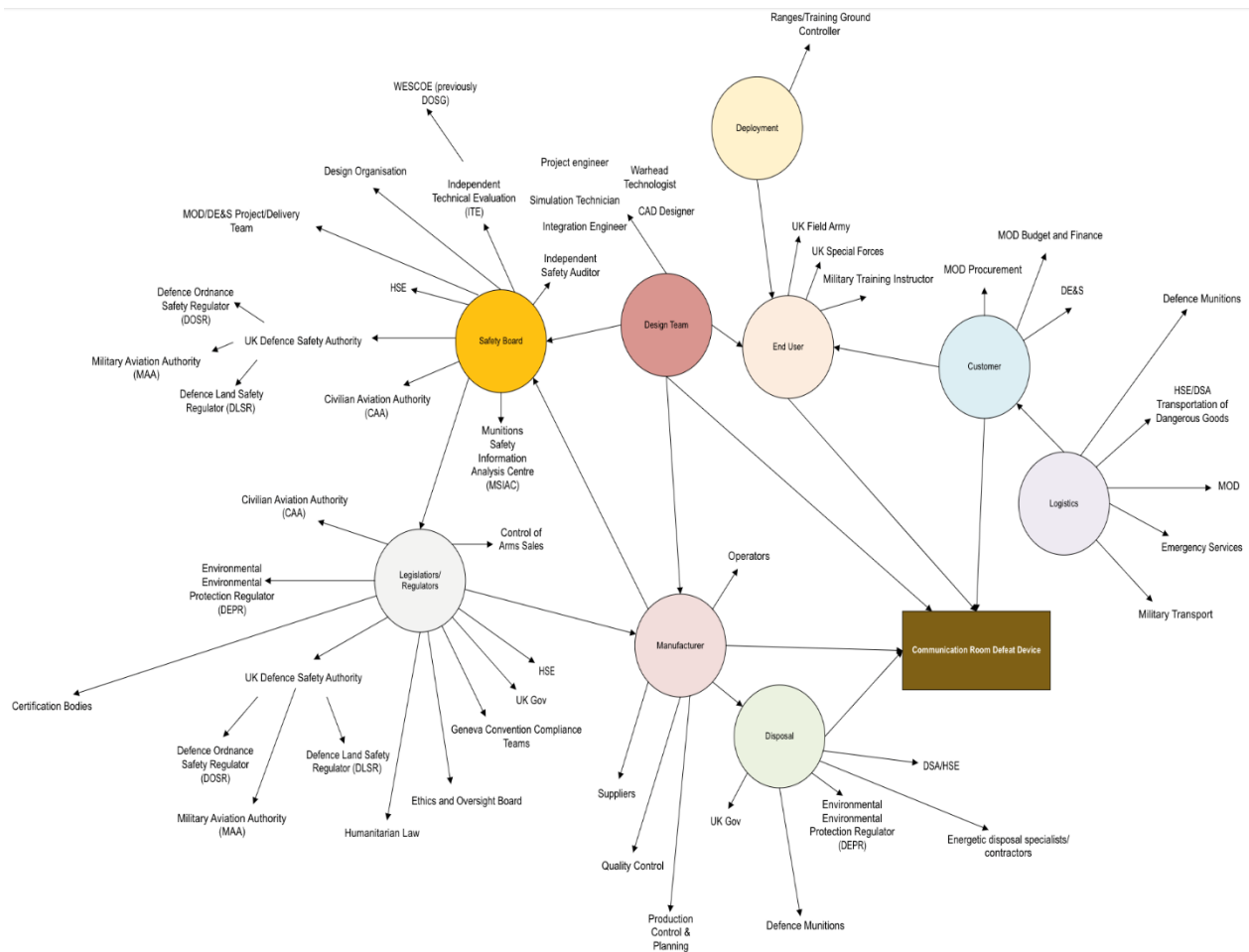


Figure 1 – Stakeholder Map

Following this activity, the full requirement set was frozen to prevent requirement creep [2]. The full Gemba visit report is included in Appendix 1.

2.2. Combined Requirement Set

Ref	Requirement Description	Originator	Category	Manufacturing Implication
R1	The system shall be capable of traveling a minimum distance of 100 meters to reach the target.	Customer	Accuracy	Requires consistent mass and aerodynamic profile.
R2	The system shall be capable of traveling upwards by at least two stories (~8 meters) to reach the second-floor target.	Customer	Accuracy	Requires structural robustness and drone lift capability.
R3	The system shall be able to accurately penetrate a 2m x 1m window.	Designer	Accuracy	Requires controlled mass, geometry, and trajectory stability.
R4	The system shall be able to penetrate external cavity block wall to enter the designated room.	Designer	Accuracy / Effectiveness	Requires adequate charge performance and fill geometry precision.
R5	The system may avoid environmental obstructions in path to target.	Designer	Accuracy	Minimal manufacturing impact; affects drone flight path planning.
R6	The system may include a targeting mechanism (e.g., laser guidance, GPS, or inertial navigation) to improve accuracy over the required range.	Designer	Accuracy	Requires interface compatibility and modular mounting features.
R7	The system shall neutralize communication capabilities within the entire 10m x 8m x 4m target area.	Customer	Effectiveness	Requires consistent fill quality and detonation performance.
R8	The system should be designed so that its effect is limited to the target room and does not impact adjacent rooms.	Customer	Effectiveness	Requires controlled NEQ, directional charge shaping, and containment.
R9	The system may be designed so that injuries to occupants are minimised.	Customer	Effectiveness / Safety	Further drives NEQ reduction and precision targeting.
R10	The system may operate in a covert manor.	Customer	Signature Management	Requires low-profile, lightweight payloads and compact assembly.
R11	The system should be designed to produce the same effect each time it is deployed under identical conditions.	Designer	Repeatability	Requires strict process control, cavity fill accuracy, and assembly consistency.
R12	The system shall function as an OME device, utilizing an explosive event to achieve the desired effect.	Customer	Explosive Function	Requires qualified explosive fill, safe handling, and validated initiation systems.
R13	The system shall detonate as intended when initiated.	Designer	Explosive Function	Requires integration checks and initiation system QA.
R14	The system shall include safeguards to prevent accidental initiation during its lifecycle.	Designer	Safety	Requires ESD control, inert handling stages, and verified safety interlocks.
R15	The system shall remain stable under expected environmental conditions.	Designer	Safety	Requires environmental monitoring during fill processing and packaging.
R16	The system shall comply with handling & storage regulations.	Designer	Compliance	Requires use of REACH-compliant materials, safe packaging, and appropriate labelling.
R17	The system shall be man portable.	Designer	Logistics	Limits total mass; promotes modular build and sub-assembly handling.

Table 1 – Full Requirements List

2.3. Requirement Prioritisation via Pairwise Comparison

A pairwise comparison was used to rank the system requirements by importance to ensure design efforts focused on key functional needs [3].

The highest-ranked requirement was:

“The system shall neutralize communication capabilities within the entire 10m x 8m x 4m target area”, confirming it as the core objective.

Other high-priority requirements included:

- Penetration of external cavity block wall
- Accurate entry through a 2m x 1m window
- Effect limited to the target room

These rankings guided later design decisions. Results are shown in Figure 2.

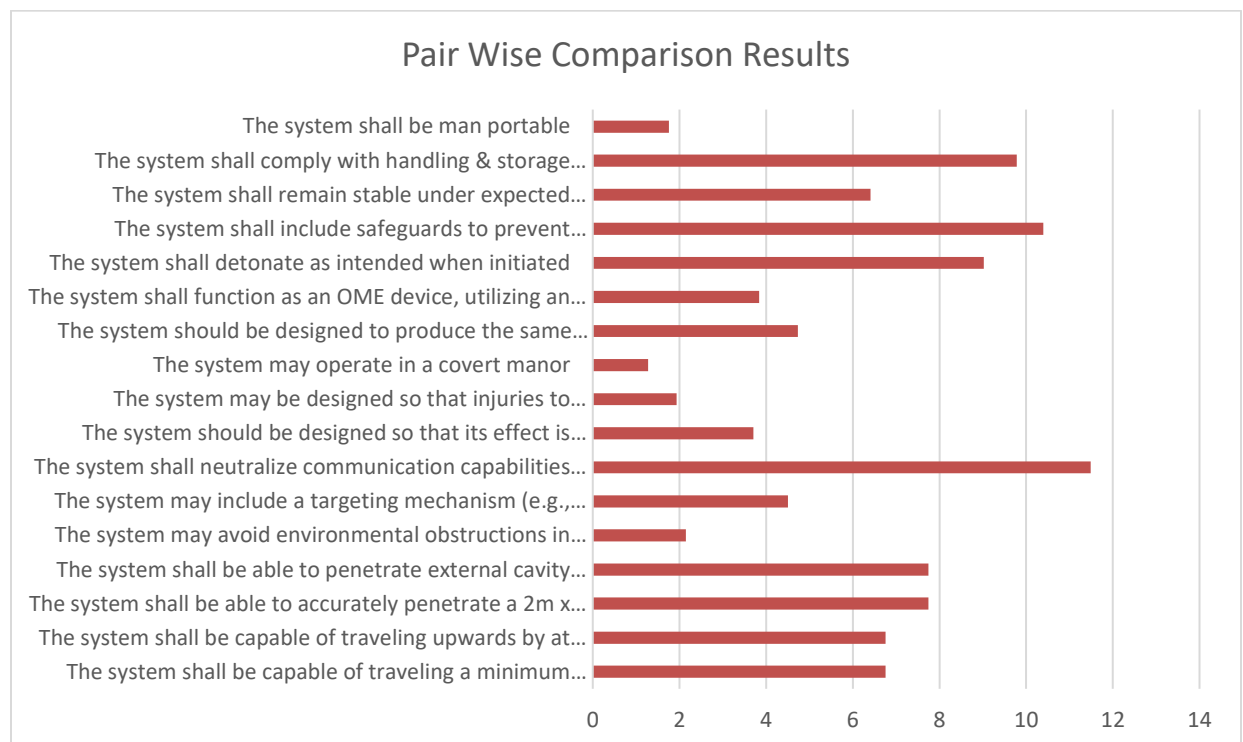


Figure 2 – Pairwise comparison results

3. Design Choice Rational

To progress from requirements to a manufacturable design, design book tools were used to evaluate system functions, compare concepts and identify critical features.

Quality Function Deployment (QFD1) results (Figure 3) highlighted the most important system functions: assemble system, enter target room and deliver effect. These functions guided technical focus across design stages.

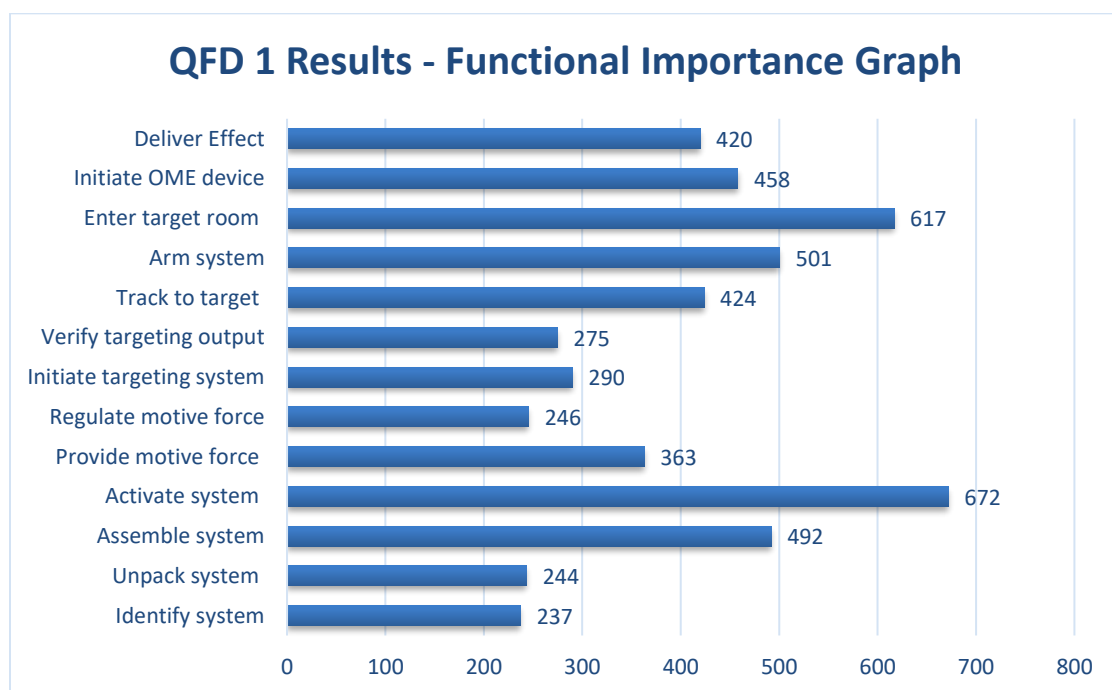


Figure 3 – QFD 1 Results

Function Means Analysis (Figure 4) generated options for fulfilling each function. This informed concept development and identified viable combinations of technical solutions.

Function	Means														
Identify system	Operator Recognition	Colour Code	Digital Interface	RFID Tag	Barcode	QR code	AR Overlay	Dimension	Smartphone Application	Biometric Access	Mission Card	Markings	Labelling	Mechanical keying	Case
Unpack system	Manual Unpacking	prepack-ready-to-use	Quick Release	Pull Tab	pressure launched system	breakaway casing	Self Deploying container	Drop Pod	Tear away packaging	Collapsible unit	Locks	Magnets	pre-scored packaging	Case	
Assemble system	Operator Manual Assembly	Pre-assembled system	Snap fit	Tool-assisted	Self locking components	Magnetic coupling	Threads	Adhesive	Collapsible unit	Pin Hinges	Velcro	Compression fittings	Spring Loaded	Modular system	
Activate system	Switch	Wireless activation	Self activated (AI)	Proximity activation	Time delay	Kinetic	Environmental trigger	Biometric Activation	password	Key	Touchscreen	Voice	Magnetic trigger	Shock	
Provide motive force	Thrown	Rocket	Mortar	Gun Launched	Helicopter	Tracks	Wheels	Pneumatic Launch	Spring	Glide Assisted	Quadcopter				
Regulate motive force	Throttle	Variable thruster	Aerodynamics control surface	Gyroscope	Program flight path	Thrust vectoring	parachute	Air brakes	Electric motor variation	Energy recovery system	one off propulsion				
Initiate targeting system	optical sighting	Laser Designator	GPS	Radar	Infrared	RF signal	Artificial Intelligence	Object recognition	Lock on after launch (LOAL)	LIDAR	Operator designation	Electromagnetic emissions tracking			
Verify targeting output	Visual	Heads Up display	IR	Radar	Optical verification	AI	GPS coordinate verification	Inertia	Pre strike authorisation	Laser					
Track to target	Laser	GPS	Gyroscopic	Optical Tracking	Operator Controlled	Infrared	Radar homing	RF tracking	AI	Terrain effect flight	Beacon homing				
Arm system	Switch	Remote arming command	Time delay	Environmental trigger	proximity	GPS	Accelerometer	Optical	RF detection						
Enter target room	Shape charge penetration	HE Blast	KE penetration	Thermobaric Charge	EFP	reinforced nose cone	spring loaded spike								
Initiate OME device	Impact fuse	Timed Fuse	Proximity Fuse	Operator Command-detonated	Barometric Fuse	Bridge wire									
Deliver Effect	Blast	Frag	EMP	KE Penetration	Shaped Charge	Thermobaric	Flechette								

figure 4 – Function Means Analysis

Three system concepts were proposed (Figure 5):

1. Drone-delivered warhead (selected)
2. Ground-launched warhead
3. Bunker-buster (baseline)

Criteria	Concept 1: Drone-Delivered Warhead	Concept 2: Ground-Launched Smaller Warhead	Concept 3: Current Bunker Buster System
Delivery Method	Personnel-operated drone to target	Ground-launched from a fixed position	Shoulder-launched
Warhead Size	Moderate, optimized for precision	Smaller than current system, targeted effect	Large, designed for hardened structures
Collateral Damage	Lower, controlled targeting	Reduced compared to current system	High, affecting adjacent rooms and structures
Accuracy	High, direct aerial placement	Moderate, depends on launch stability	High, but excessive damage
Operational Risk	Requires remote operation, risk of drone interception	Operator exposed at launch position	Operator exposed at launch position
Stealth & Reaction Time	High—target has little reaction time	Moderate—faster than current system	Moderate—quick effect but large signature

Figure 5 – System Concepts

Concept 1 was chosen due to accuracy, lower collateral damage and reduced operator risk [4]. A System Pugh Matrix (Figure 6) confirmed its performance advantage.

	Relative Importance Equal	Concept 1	Concept 2	Concept 3
WHATs - Customer Requirements				
The system shall be capable of traveling a minimum distance of 100 meters to reach the target.	5.517	2	2	0
The system shall be capable of traveling upwards by at least two stories (~8 meters) to reach the second-floor target.	6.48	2	2	0
The system shall be able to accurately penetrate a 2m x 1m window or external cavity block wall to enter the designated room.	5.517	1	0	0
The system may avoid environmental obstructions in path to target	4.862	2	1	0
The system may include a targeting mechanism (e.g., laser guidance, GPS, or inertial navigation) to improve accuracy over the required range.	3.034	0	1	0
The system shall neutralize communication capabilities within the entire 10m x 8m x 4m target area.	4.755	1	2	0
The system should be designed so that its effect is limited to the target room and does not impact adjacent rooms.	12.22	1	-2	0
The system may be designed so that injuries to occupants are minimised.	10.4	-1	-2	0
The system may operate in a covert manor	11.95	1	0	0
The system should be designed to produce the same effect each time it is deployed under identical conditions	4.093	1	1	0
The system shall function as an OME device, utilizing an explosive event to achieve the desired effect.	4.387	2	2	0
The system shall detonate as intended when initiated	5.395	1	0	0
The system shall include safeguards to prevent accidental initiation during its lifecycle	3.453	2	1	0
The system shall remain stable under expected environmental conditions	3.222	2	1	0
The system shall comply with handling & storage regulations	7.11	2	1	0
The system shall be man portable	4.702	2	1	0
Total Score		112.993	27.504	0

Figure 6 – System Pugh Matrix

QFD2 (Figure 7) was used to link functions to enabling features [5]. Key outputs included *modular system*, *manual assembly* and *proximity initiation*, which influenced interface design and component layout.

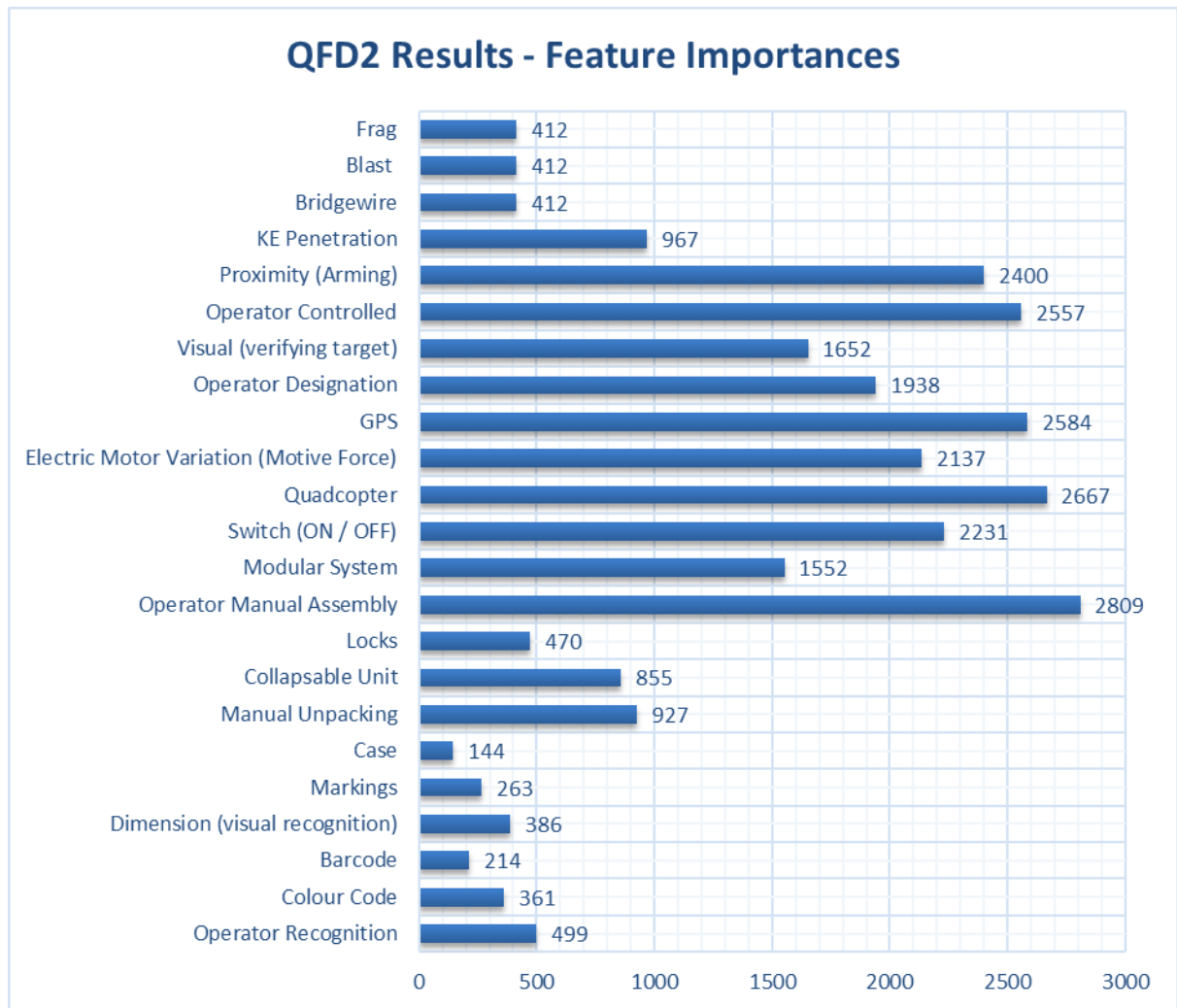


Figure 7 – QFD 2 Results

A Design Failure modes and effects analysis (DFMEA) (Figure 8) identified major risks in fill handling, assembly and initiation. Mitigations included suitably qualified and experience person (SQEP) operator requirements, robust procedures and ergonomic jigs.

Top Design Failure Risks (Pre-Mitigation)					Top Design Failure Risks (Post-Mitigation)				
Design Feature	Failure Mode	Description	Pre Mitigated RPN	Post Mitigated RPN	Design Feature	Failure Mode	Description	RPN	
Manual unpack	No feature	Failure to unpack system results in mission failure	144	48	Operator command detonated	No feature	Operator failure, System failure	64	
Manual unpack	Too little feature	Failure to completely unpack Weapon system results in mission failure	144	48	Operator controlled	Too little feature	Weapon System tracking too loose. Potential for attack sequence to begin on incorrect target.	54	
Operator manual assembly	Wrong feature	Weapon System incorrectly assembled	144	48	Operator manual assembly	Wrong feature	Weapon System incorrectly assembled	48	
Manual unpack	Intermittent feature	Failure to completely unpack Weapon system results in mission	144	32	Manual unpack	No feature	Failure to unpack system results in mission failure	48	
GPS	Wrong feature	Drone location incorrect	140	36	Manual unpack	Too little feature	Failure to completely unpack system results in mission failure	48	
Operator controlled	Too little feature	Weapon System tracking too loose. Potential for attack sequence to begin on incorrect target.	108	54	Markings	No feature	Failure to identify weapon system could result in deployment of incorrect system and failed mission.	48	
Locks	No feature	No locks present, resulting in unsecured case and potential damage to Weapon System in Transit.	108	24	Markings	Intermittent feature	Failure to identify weapon system could result in deployment of incorrect system and failed mission.	48	
Locks	Too little feature	No locks present, resulting in unsecured case and potential damage to Weapon System in Transit.	108	24	Markings	Wrong feature	Failure to identify weapon system could result in deployment of incorrect system and failed mission.	48	
Locks	Wrong feature	Wrong locks present, resulting in unsecured case and potential damage to Weapon System in Transit.	108	24	Colour code	Wrong feature	Failure to identify weapon system could result in deployment of incorrect system and failed mission.	48	

Figure 8 – DFMEA results

A P-diagram (Figure 9) defined system inputs, outputs and noise factors.

Manufacturing contributed here to address risks like fill variability, material degradation and environmental effects.

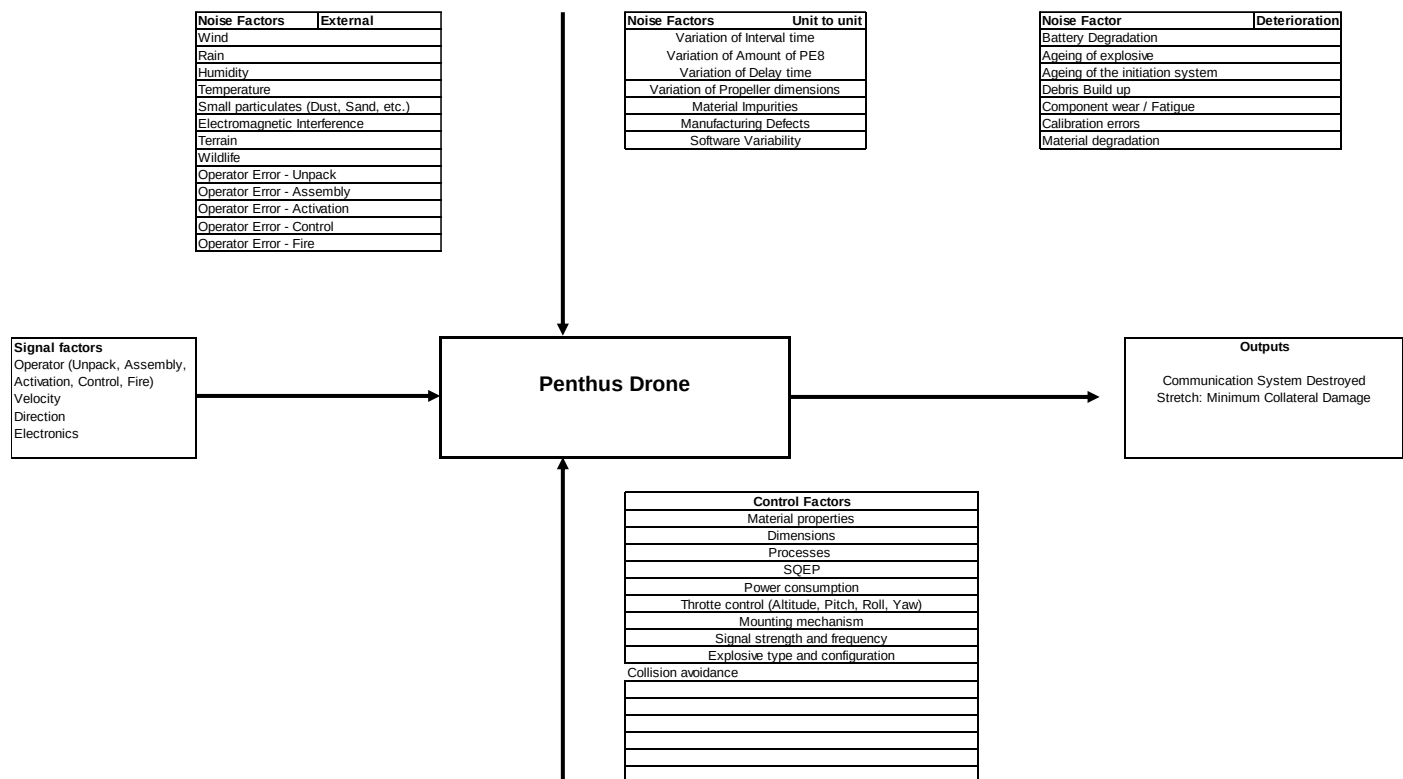


Figure 9 – P- Diagram

A What why (Figure 10) confirmed that explosive fill variation, operator error and environmental stability were top noise Factors. These directly influenced process design and aligned with points defined in the DFMEA.

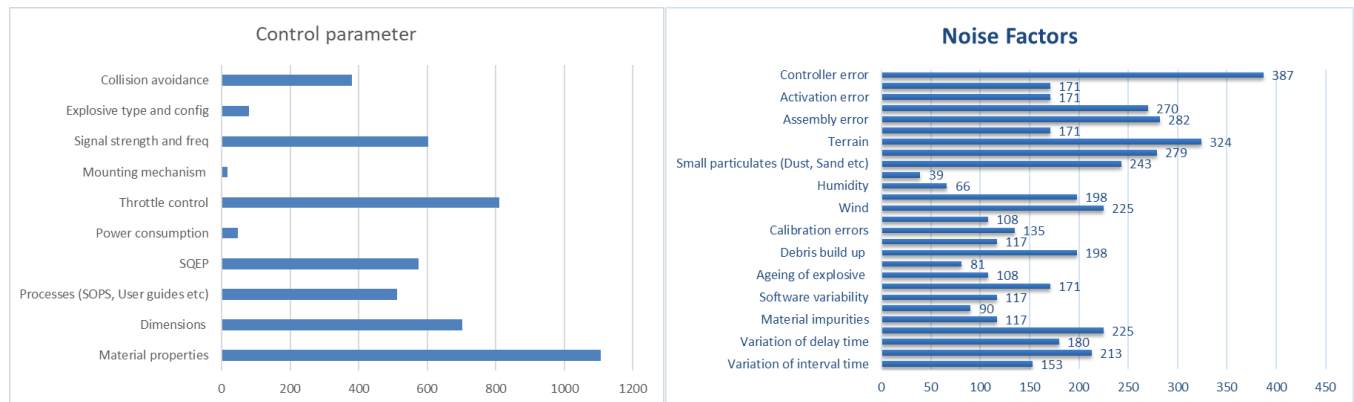


Figure 10 – Key controls and Noise Factors from What Why

A final subsystem QFD identified the explosive fill as the most critical area due to “deliver effect being an initial primary” requirement, as well as the choice to have a commercial off the shelf drone to eliminate many requirements the team had SQEP in. Manufacturing then led a subsequent workbook to ensure it could be produced safely, repeatably and in compliance with system constraints (section 4 onwards). The Final warhead design concept is shown in Figure 11, which was supplied to the manufacturer for manufacturing capability assessment.

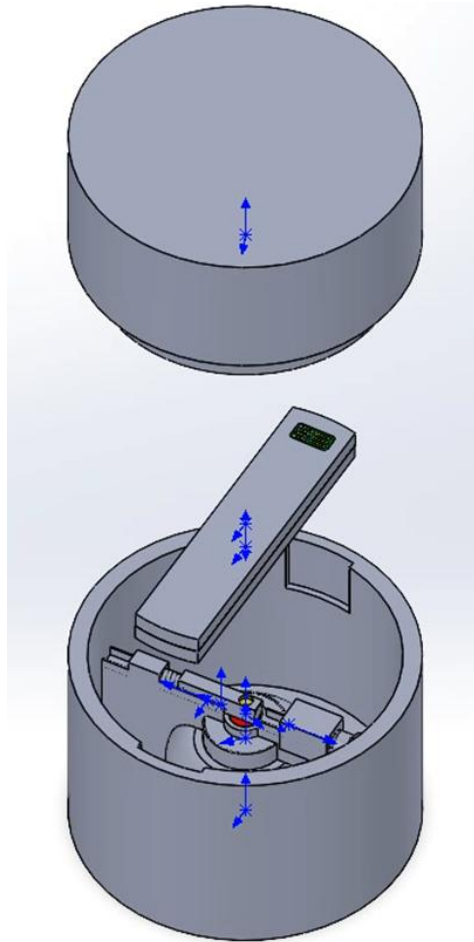


Figure 11 – Modular Warhead Concept Design.

4. Manufacturing

4.1. Key Customer Manufacturing Requirements

Manufacturing was engaged early in the project to assess feasibility of key system requirements. This was supported by participation in the Gemba visit (Appendix 1), allowing direct evaluation of practical handling, integration and disposal implications. The requirements with the most significant manufacturing implications were drawn from the full set in Section 2.2.

Table 2 summarises manufacturing stakeholder priorities, including cost, quality and safety drivers. These were used to interpret the customer's needs from a production perspective.

Ref	Requirement Description	Manufacturing Implication
R8	Effect limited to target room	Required NEQ control, consistent fill geometry, and directional design
R11	Repeatable effect	Drove strict tolerance control, SOPs, and quality checks
R12	Explosive-based function	Required validated fill and licensed procedures
R13	Reliable initiation	Affected detonator alignment, QA checks, and interface design
R14	Accidental initiation safeguards	ESD precautions, operator controls, and risk-mitigated assembly
R15	Environmental stability	Required temp/humidity-controlled filling environments
R16	Storage and handling compliance	Required REACH-compliant materials and packaging protocols
R17	Man-portable system	Constrained overall weight, requiring modular builds

Table 2 – key manufacturing dependant customer requirements

These requirements were translated into system functions via QFD1 and used to shape the manufacturing concept, layout and process planning discussed in Section 4.2 onward.

4.2. Critical System Functionality

The warhead filling and integration process was identified as the most critical manufacturing function. This was confirmed via the manufacturing process flow (Figure 12) and a pairwise comparison which informed critical function vs derived process and customer requirements (Figure 3).

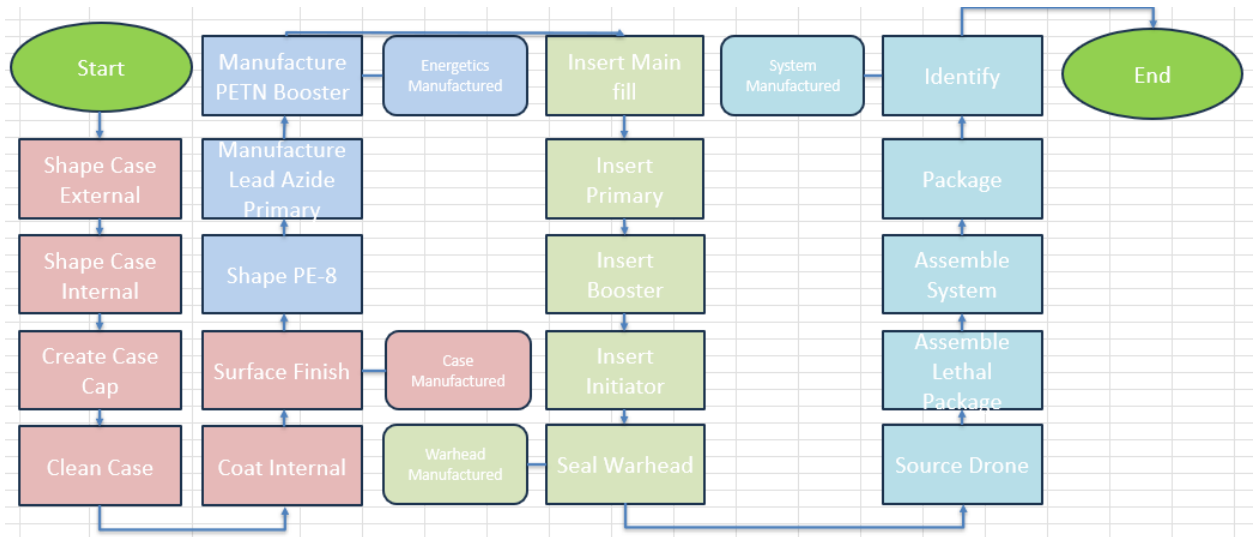


Figure 12 – Top Level Manufacturing Process Flow

Manufacturing assessed each step's impact on performance, safety and compliance. High-priority steps included:

Critical Function	Derived from Process Step	Linked Customer Requirements
Explosive fill shaping and handling	Shape PE-8, Unpackage PE-8	R8, R11, R12
Energetic component integration	Insert Primary, Insert Booster, Insert Initiator	R11, R12, R13
Final closure and sealing	Seal Warhead	R11, R14, R15
System integration	Assemble Lethal Package, Assemble System	R11, R16, R17

Table 3 – Critical Function vs Customer Requirements

These activities were most sensitive to process variation and introduced the greatest manufacturing risk. Their alignment with key customer needs ensured early design decisions considered manufacturability and allowed for appropriate mitigation strategies in process planning and quality control. One example of this alignment was the adoption of a drop-in charge configuration to enable safe and repeatable loading of the selected explosive. This choice, made to simplify the manufacture of small NEQ charges, required the design team to revise the internal architecture of the warhead. The cavity was adapted to accommodate solid drop-in units rather than a liquid fill, ensuring consistency in fill mass and eliminating the complexity of cast-cure operations. This early design-for-manufacture decision reduced handling risk, simplified tooling and supported repeatable explosive performance.

4.3. Concept Derivation and Design Choices through manufacturing req

Within the manufacturing domain, design decisions were informed by the results of a dedicated manufacturing QFD1. This tool mapped stakeholder manufacturing requirements such as cost control, repeatability, compliance and safety against each identified process step within the full manufacturing sequence. The objective was to determine which activities were most critical to meeting overall system performance and regulatory obligations.

The QFD1 output identified a clear set of high-impact processes. As shown in the Process Importance Chart (Figure 13).

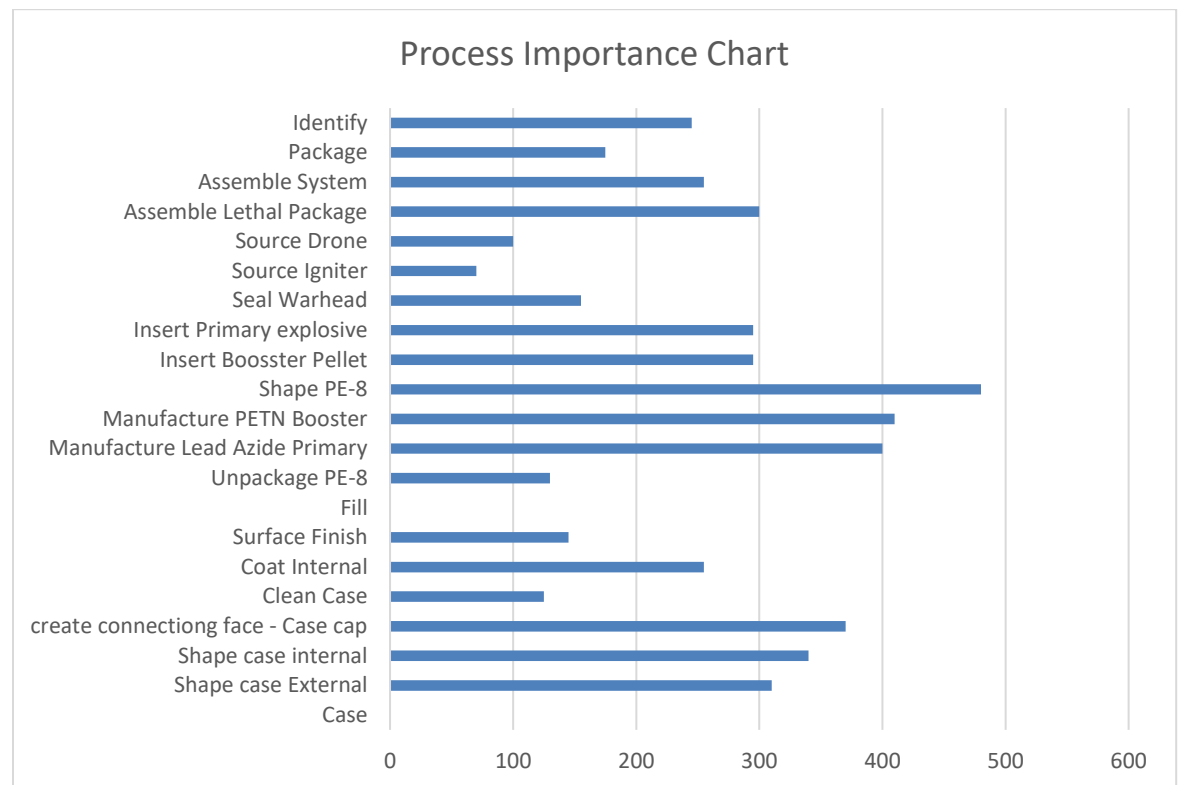


Figure 13 – Manufacturing QFD1 Results

the manufacture and integration of energetic materials ranked highest.

These included:

- Shaping of PE-8
- Manufacture of lead azide and PETN
- Insertion of boosters and primaries

These operations were directly linked to the system's primary function of neutralising the communications centre (Requirement R7) and to supporting consistent repeatable effect delivery (Requirement R11). They

also carried significant safety and regulatory weight (Requirements R12–R15).

This prioritisation allowed the manufacturing team to focus engineering effort on process development where it was most required and to allocate downstream design refinement to operations where variation or failure would critically affect system outcome. The results of this prioritisation were carried forward into control planning.

4.4. The Manufacturing Process & Critical Design Feature

Follow on activity focused on shaping and handling of PE-8 explosive.

This process directly supports the system's primary function of neutralising the communications centre (Requirement R7) and presents high safety, repeatability and compliance demands (R11–R15).

The importance scoring results from QFD 1 (Figure 13) confirmed that shaping PE-8, carried the greatest influence on overall manufacturing success making it the highest priority critical design feature. As a result, these steps were prioritised for detailed process development.

Shaping of PE-8 was approached by evaluating multiple options through Function Means Analysis (Figure 14 – PE-8 shaping in red) and QFD2 results (Figure 15). While pressing offered good compaction properties, it

posed an unacceptable detonation risk under high pressure and was ruled out as not reasonably practicable [6]. Extrusion was selected for its lower-pressure profile, consistent output and ability to support a drop-in loading method.

Function	Means				
Case					
Shape case External	Manual Lathe	CNC Mill	5 Axis CNC	Manual Mill	CNC Lathe
Shape case internal	Manual Lathe	CNC Mill	5 Axis CNC	Manual Mill	CNC Lathe
create connecting face - Case cap	Manual Lathe	CNC Mill	5 Axis CNC	Manual Mill	CNC Lathe
Clean Case	Ultrasonic Bath	Brush and Blow	Bath clean	Vacuum	
Coat Internal	Line	Plastic	PTFE	Polyethylene	
Surface Finish	Grind	Mill	Machined Finish		
Fill					
Unpackage PE-8	Hand				
Manufacture Lead Azide Primary	Cast Curing	Pressing	Extrusion		
Manufacture PETN Booster	Cast Curing	Pressing	Extrusion		
Shape PE-8	Hand Shape	Extrude	Press		
Fit Booster	Hand Assembly	Robotic Assembly	Push Fit		
Fit Primary	Hand Assembly	Robotic Assembly	Push Fit		
Seal Warhead	Loctite	PTFE			
Source Igniter	COTS				
Source Drone	COTS				
Assemble Lethal Package	Hand Assembly				
Assemble System	Hand Assembly	Robotic Assembly			
Package	Wooden Box	Metal Container	Foam Inserts	Antistatic bag	Bubble Wrap
Identify					

Figure 14 – Manufacture Function Means

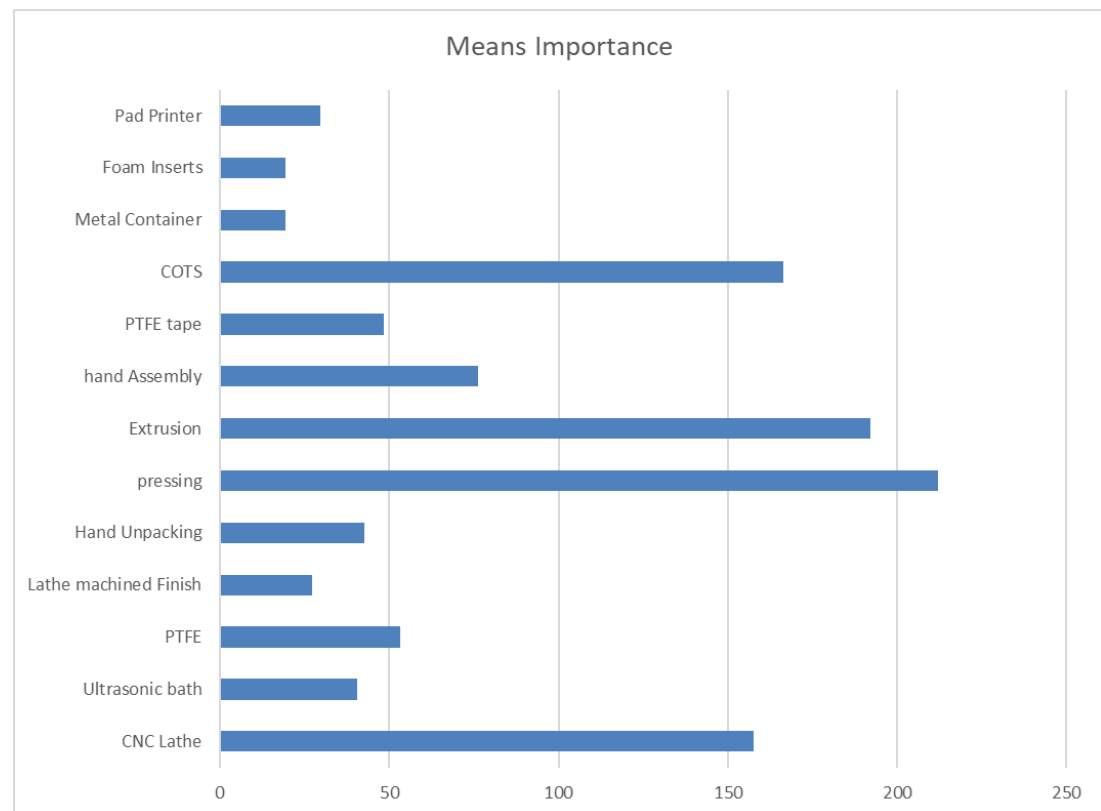


Figure 15 – QFD2 Means Importance

The extrusion line (Figure 16) uses a single-screw barrel with feed, compression and metering zones (Figure 17). Shaped pellets are transferred by conveyor to a cooling carousel (Figure 18), supporting safe collection with minimal manual handling.



Figure 16 – Extrusion Machinery

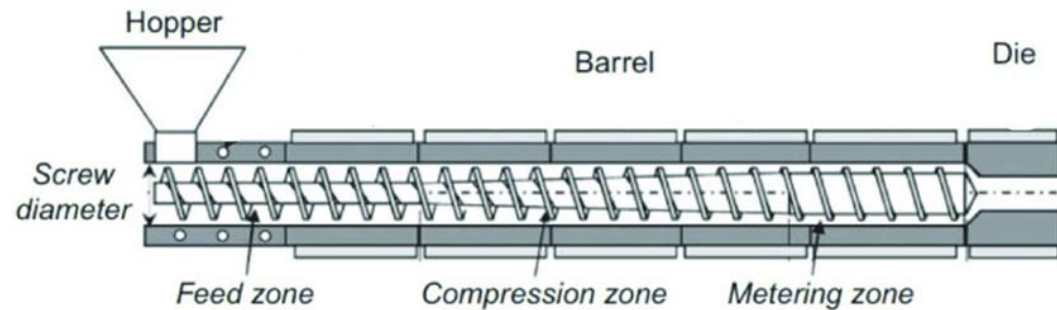


Figure 17 – Internal Workings of Extrusion Machinery

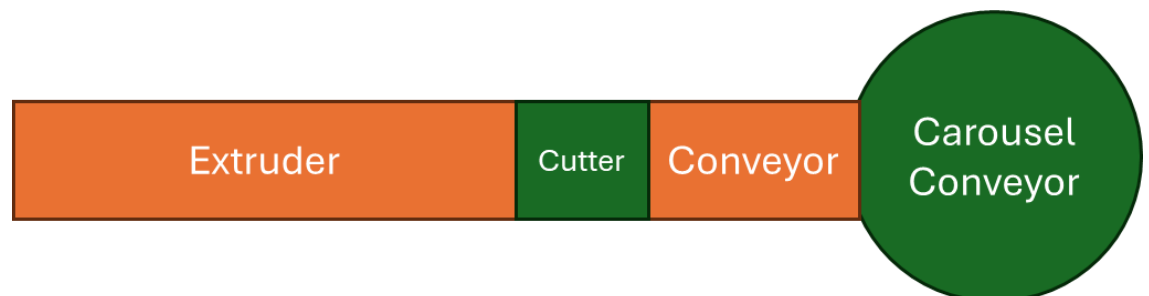


Figure 18 – Birds Eye view of complete extrusion process

The process is governed by a defined operation protocol, shortened variation shown in Figure 19.

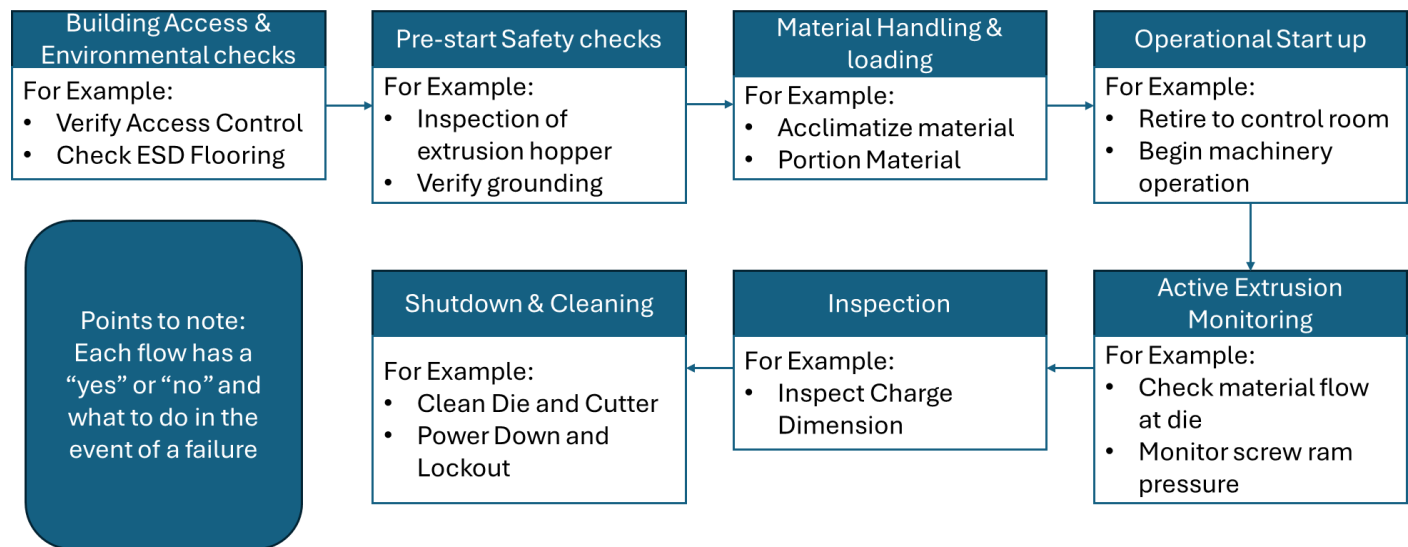


Figure 19 – Process Flow for Extrusion Process

This structure ensures consistent production of the most critical component in the warhead, this process flow also informed the PFMEA generation.

4.5. Potential Failure Modes

A detailed PFMEA was conducted to assess the risks associated with PE-8 extrusion. This analysis focused on failure modes that could affect safety, product quality and compliance with the MSER [7].

The PFMEA used post-control scoring only, as risk mitigation measures were implemented prior to assessment in line with mandatory regulatory

controls. The complete PFMEA is provided in Appendix 2, with the highest-risk operations summarised in Table 4.

Risk Priority Numbers (RPNs) were derived from severity, occurrence and detection scores. Notably, the most critical failure modes were not those with the highest severity alone. Instead, the highest-priority risks were those where two or more scoring factors were simultaneously high. For example:

- A detonation risk that is easily detectable may present less operational concern.
- A moderate-severity event that is both hard to detect and frequent becomes high-risk due to limited recovery opportunity.

Operation No.	Operation Description	Failure Mode	Effect of Failure	RPN
13	Lubricate with approved dry film lubricant	Too much lubricant	Contamination of explosive material	48
10	Ensure Extrusion Drum grounding cable is secure	Grounding cable damaged	Electrostatic discharge → potential ignition	45
11	Inspect Extruder Screw Ram	Screw ram damaged	Pellet inconsistency; risk of future contamination	45
14	Perform dry test spin	Screw ram moves too quickly	Overpressure, machinery damage, extrusion instability	32
18	Verify temperature control	Temp control non-functional	Uncontrolled heating; explosive instability	30
8	Inspect Extrusion Drum	Drum contaminated	Product contamination or cross-batch reactivity	30
9	Check Extrusion Drum for moisture	Moisture present	Instability in fill; pre-initiation hazard	30

Table 4 – High Risk Failure Modes from PFMEA

These failure modes primarily relate to material contamination, thermal deviation, electrostatic discharge and mechanical instability. Each

represents a potential threat to the system's functional repeatability (R11), terminal effect (R7) and overall safe operation (R14, R15).

4.6. Critical Process Steps

Based on the risk evaluation in Section 4.6, several operations within the PE-8 extrusion workflow were identified as critical process steps due to their elevated RPNs, direct influence on safety and impact on product consistency and performance.

Each step listed below either:

- Involves direct handling of energetic materials
- Controls a hazard pathway (e.g. pressure, electrostatic discharge)
- Has a history of failure modes with high severity and low detectability

Table 5 shows process steps are designated as critical for control, monitoring and inspection.

Critical Step	Description	Reason for Criticality
Grounding Cable Inspection	Ensure electrical grounding is intact and verified before operation	Prevents static discharge → ignition (RPN 45)
Screw Ram Inspection	Assess for wear, residue, or scoring before use	Affects fill uniformity, introduces contamination risk (RPN 45)
Temperature Control Verification	Confirm thermal controls are operational and stable	Prevents thermal runaway or sub-spec fill behaviour (RPN 30)
Dry Film Lubrication Application	Apply correct volume of lubricant to ram	Excess lubricant can contaminate explosive material (RPN 48)
Extrusion Drum Inspection (Clean/Dry)	Ensure no moisture or residue present	Moisture introduces thermal instability, contamination (RPNs 30/30)
Dry Test Spin of Screw Ram	Confirm correct motion profile pre-extrusion	Prevents pressure anomalies or mechanical failure (RPN 32)

Table 5 – Critical Process Steps

These steps are supported by formal Standard Operating Procedures (SOPs), operator checklists and visual inspection protocols. Where applicable, steps also include interlocks, start-up testing and sign-off requirements by trained SQEP personnel.

These controls ensure that the most risk-sensitive parts of the manufacturing process are consistently executed to standard, directly supporting requirements R7 (effectiveness), R11 (repeatability), R14 (safety) and R15 (stability).

4.7. Process Control measures

A Process Control Plan (PCP) was developed as the final document in the trilogy of manufacturing risk management tools, alongside the PFMEA (Section 4.6) and Process Flow Diagram (Section 4.2). This documentation set was created to ensure compliance with the MSER and to systematically control operations that present the greatest risk to product quality and personnel safety.

The PCP defines the control methods, measurable parameters, control frequencies and escalation plan for every step of the PE-8 extrusion process. Focus was given to high-risk operations identified through the PFMEA, with key controls summarised in Table 6.

Op No.	Operation Description	Control Parameter	Control Method	Frequency	Reaction Plan
10	Ensure grounding cable is secure	Electrical continuity	Visual inspection	Pre-shift	Replace cable/clamp; reverify
11	Inspect Screw Ram for scoring	Mechanical integrity	Visual inspection	Pre-shift	Replace or escalate
13	Apply dry film lubricant	Lubricant coverage	Visual + touch test	Pre-shift	Clean and reapply lubricant
14	Perform dry test spin	Rotational smoothness	Manual test spin	Pre-shift	Inspect drive & bearings
18	Verify temperature control	Die head temp (°C)	Thermocouple sensor	Hourly during operation	Stop process; inspect heating system
8	Inspect Extrusion Drum	Cleanliness (internal)	Visual inspection	Pre-shift	Clean again; report if recurring
9	Check for moisture in drum	Internal moisture	Lint-free wipe test	Pre-shift	Dry drum; adjust HVAC or pause process

Table 6 - High Risk Process, Process Controls

All process controls are built around five core enablers, shown in Figure 20:

- Robust Standard Operating Procedures (SOPs)
- Defined operator checklists
- Regular training and competency verification
- Proactive preventative maintenance
- Independent management inspection and sign-off

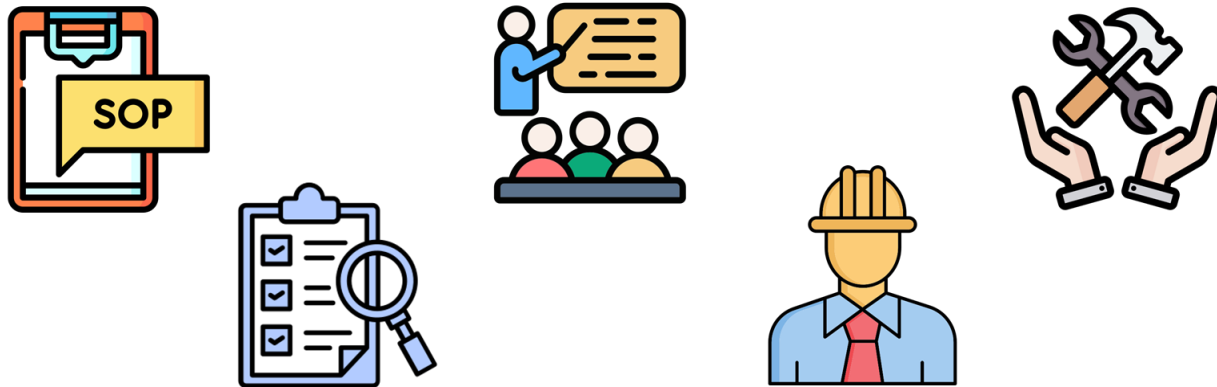


Figure 20 – 5 key process controls

Within process control, as standard, administrative controls have the most variance. this is why a combination of administrative controls are used concurrently [8].

4.8. Waste Disposal route

Waste generated during the manufacturing process was assessed for both its regulatory classification and safe disposal method. The extrusion of PE-8 introduces unique challenges due to the presence of high-energy materials and contamination risks inherent in the equipment and material handling.

4.8.1. Classification of Manufacturing Waste:

Waste was categorised into two main types:

- Hazardous Waste: Includes off-spec extrudate, contaminated dies and cleaning residues containing PE-8 traces. These are governed under the ENVIRONMENTAL PROTECTION ACT

1990 [9] and the HAZARDOUS WASTE REGULATIONS 2005 [10].

- Non-hazardous Waste: Includes general packaging, PPE and maintenance disposables with no contamination.

Disposal Method:

- Hazardous explosive residues (e.g. rejected extrudate or contaminated wipes) will be disposed of in accordance with the MSER 2005 and paragraph 431 of its ACOP, which mandates hazard identification and risk assessment before disposal.
- The selected disposal method is detonation, in line with practices for small-batch energetic waste. This method was chosen due to:
 - The isolated nature of the disposal site (Bramble Island, Essex)
 - Avoidance of secondary hazards produced by chemical neutralisation
- Non-hazardous waste will be handled through standard waste management channels in accordance with ISO 14001:2015 principles [11] applied across the production process.

4.8.2. Recoverability Note:

- In some cases, if extrudate fails due to form factor only (e.g. pellet deformation but not chemical instability), material may be reprocessed, reducing unnecessary disposal.

5. Design review chair feedback response – manufacturing specific

Panel Comment / Question	Manufacturing Response
How do you get clearance onto the drone? (Vibration, bumping into things?)	The mounting and packaging of the warhead within the drone were addressed during the Design for Manufacture phase. Physical isolation was implemented using soft buffer mountings to mitigate vibration and prevent resonance from damaging the fill. CAD clearances were validated using mock-up envelope modelling.
Design for manufacture exercise... tools used?	The design was developed using the Design Book methodology including Function-Means Analysis, QFD 1 and 2, PFMEA, and finally the Process Control Plan (PCP). These were supported by a dedicated extrusion flow process map and risk-traceable design trade-offs. resulting in the output in figure 21.
Extruder highest area of risk.....	This was identified early through the QFD and confirmed in PFMEA. Control measures (Section 4.7) focused on grounding, pressure regulation, material preconditioning, and extrusion temperature control. Operator procedures were backed by MSER compliance controls.
Trilogy... explain this in the report	The manufacturing section included a breakdown of the three-tier documentation system: Process Flow Diagram, PFMEA, and Process Control Plan (PCP), which together fulfil regulatory obligations and define manufacturing control strategy. See Section 4.8.
Process steps brought down and highlighted	Yes, Section 4.6 outlines critical process steps, and Section 4.7 links those to specific controls. These steps were drawn from PFMEA risk scores and show clear traceability from risk to mitigation.
PCP developed	The Process Control Plan is fully developed and included in Appendix 3. Key controls for high-risk operations are summarised in Table 6. Controls were structured around SOPs, checklists, inspection routines, and reaction plans.
Key sources of human error??	Human error was assessed in the PFMEA. Common error sources include incorrect material loading, failure to confirm system ground, and improper lubricant application. Each of these is controlled through checklists, SQEP operator roles, and pre-shift inspections as detailed in Sections 4.5 and 4.7.
Remember to cascade analysis back up the ladder	Analysis from Function Means and QFD 2 was used to define critical subsystem requirements (e.g. warhead fill delivery), which directly influenced manufacturing tolerances and material handling choices. This linkage is captured through the Design for X (DFx) integration approach.

Table 7 - Manufacturing Design Review Feedback Question Answers

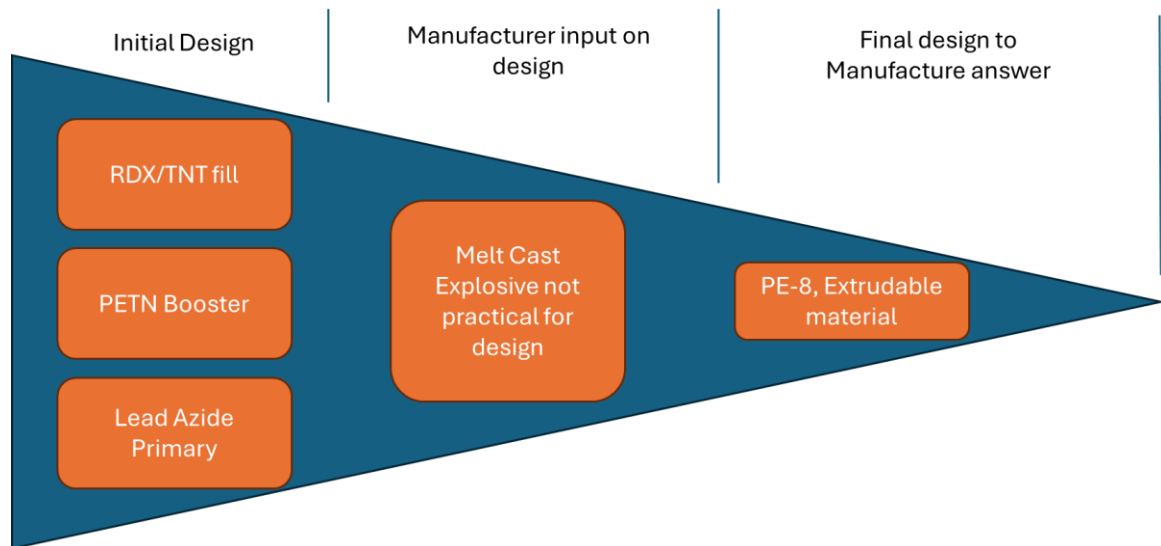


Figure 21 – Design for Manufacture Outputs

6. Conclusion

This study examined the application of systems engineering methods to develop a manufacturable solution to an OME design problem. The focus was on how manufacturing tools and processes could be used to reduce risk, ensure compliance and influence early-stage design decisions. The analysis answered the key research question: how can manufacturing constraints and risk management be used to drive a safe and effective warhead design for a drone-delivered precision system?

While the study successfully developed and validated a production-ready approach for PE-8 extrusion, limitations included a lack of live process validation due to the conceptual nature of the project. Real-world testing of the extrusion line and integration into the drone platform would be required to confirm tolerances, environmental performance and full-system reliability.

The findings support the importance of early manufacturing involvement in the design lifecycle. Manufacturing inputs directly influenced material selection, warhead geometry, risk mitigation and waste handling. The use of tools such as PFMEA and the Process Control Plan ensured alignment with MSER and demonstrated how structured analysis supports system safety and repeatability.

Future work should include validation of the process under operational conditions, further development of automated filling and handling systems and

expanded lifecycle assessment covering in-field handling. Additional work is also recommended to evaluate alternative fill types and scalable manufacturing routes for higher production volumes.

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8. Appendix 1 – Gemba Visit

Gemba Visit Report

Gemba Visit Report – Salisbury Plain (Imber Village)

In Attendance:

- Development Team (All members)
- 2 Stakeholders
- 5 End Users

Objective:

To observe how end users engage with their existing weapon systems in an operational training environment, identifying challenges, risks, and potential areas for improvement in the new system development.

Observations:

During the visit, end users demonstrated their current system used to neutralize potential threats in an urban setting as part of a structured training exercise. The systems currently in use include:

- FGM-148 Javelin
- M141 SMAW-D

Both systems were observed in a realistic operational setting, demonstrating their compliance with both legal requirements and the mandatory performance criteria outlined in the customer's requirement set. During the exercise, both systems successfully achieved full target room destruction, including the intended communications equipment.

However, several key observations were made:

- The current systems were identified as overmatched for the requirement, causing significant collateral damage beyond the target room, affecting adjacent rooms and the floor below.
- The effect of the system was assessed as incompatible with life for any occupants in the target room and posed a significant risk of catastrophic injury to personnel in the surrounding structure.
- End users noted that between firing and impact, only seconds elapsed, meaning people in the target room had little time to react before the effect was delivered.

Key Insights from End Users:

Preferred Features in Current Systems:

- Fire-and-forget capability
- Single operator firing capability
- Two-person portability
- Soft-launch capability (*noted for improvement; see below*)
- Consistent terminal effect on target when a hit is achieved

Challenges Identified in Current Systems:

- Overmatch in urban environments, causing excessive damage beyond the intended target.
- IR seeker performance issues, leading to decreased targeting accuracy.
- Backblast hazard, which can pose risks to the firing team in confined spaces.

Conclusion:

Discussions with stakeholders and end users confirmed that a system more closely matched to the requirement would be preferable, reducing unnecessary damage to surrounding structures while still ensuring complete neutralization of the target. Stakeholders acknowledged that while minimizing reaction time in the target room is critical, achieving this does not necessarily require the system to be fully covert.

Next Steps:

Following the stakeholder engagement and Gemba visit, the refined requirement set (as per the requirement table for full details) will now guide the next phase of development through Quality Function Deployment (QFD1) and functional means analysis. The customer-driven requirements establish core performance expectations, while the designer-driven requirements, informed by operational insights, ensure practical feasibility and mission effectiveness.

9. Appendix 2 – PFMEA

Operation Number	Operation Description	Potential Failure Mode	Failure Mode Class	Potential Effects of Failure	SEV	Potential Causes	Prevention Controls	OCC	Detection Controls	DET	RP N
1	Verify access control to extrusion bay	Building Locked	Process Safety	Operators cannot access building	3	Building Lock broken key lost Key Broken	regular Maintenance Spare Keys Spare Lock	1	Inspection	1	3
		Building Left Unlocked	Process Safety	Uncontrolled access to process	3	Operator not locking building Building lock Broken Key Lost	regular Maintenance Spare Keys Spare Lock	1	inspection Key Press	1	3
		personell in and out incorrectly logged	Process Safety	Uncontrolled access to process	3	Operator not signing in	Operator Training	3	inspection Key Press Log book	1	9
2	Check ESD flooring	Flooring Damaged	Process Safety	Not ESD safe	5	Dropped Objects Sharp Object Damage foreign object damage	PPE Cleaning sharp objects linked to work stations	2	PPE Inspection tool Shadow Boards	2	20
		Flooring Dirty	Process Safety	Not ESD safe	5	Incorrect Cleaning excessive dirt tracking Incorrect cleaning Products	PPE Cleaning Close Down Cleaning Procedure COSH cupboard stocked with correct cleaning products	4	Close Down procedure Inspection	1	20
3	Ensure blast shields and interlocks are engaged	Interlock Broken	Process Safety	no System Function explosive event causing excessive injury	2	incorrect maintenance incorrect operation	Standardised Maintenance Regime Operator Training	3	start up inspection regular maintenance check	3	18
		Blast shielding Not in place	Process Safety	no System Function explosive event causing excessive injury	5	incorrect maintenance incorrect operation	Standardised Maintenance Regime Operator Training	1	start up inspection regular maintenance check	1	5
		Blast shielding	Process Safety	no System Function explosive	3	incorrect maintenance incorrect operation	Standardised Maintenance	2	start up inspection regular maintenance check	1	6

		incorrectly fitted		event causing excessive injury			Regime Operator Training				
4	Confirm area is clean and free of foreign objects	Area Not Clean	Product Quality	Cross contamination of product	2	No cleaning completed Cleaning Insufficient	Operator Training	5	Visual Inspection	1	10
5	Energize control panels and PLCs	power not provided	Process Safety	Process not operable	1	Damaged Controls no power to building incorrect operation	Maintenance operator training	3	On/Off indicator	1	3
6	Verify fire suppression system status	Fire Suppresion system in suppression process	Process Safety	Building Flooded Process damaged personell injured	5	incorrect maintenance incorrect operation	Maintenance operator training	1	Maintenance inspection Regular Maintenance check	1	5
		Fire suppression system off	Process Safety	System non functional in emergency	5	incorrect maintenance incorrect operation	Maintenance operator training	3	Maintenance inspection Regular Maintenance check SOP Checks	2	30
		Fire suppression system leaking	Process Safety	Building Flooded Process damaged personell injured	3	incorrect maintenance incorrect operation	Maintenance operator training	3	Maintenance inspection Regular Maintenance check	2	18
7	Test interlocks and emergency stop	Interlocks and E-Stops Not Functional	Process Safety	Process non Functional process functional without guards in place E-Stop non functional in emergency situation	5	incorrect maintenance incorrect operation Interlocks Tampered with Electrical Fault Incorrect progScrew Ramming	Maintenance operator training inspection start up testing	4	Visual Inspection building start up test operation	1	20
8	Inspect Extrusion Drum for	Extrusion Drum contaminate d	Product Quality	Product Contaminatio n Equipment damage	3	Incorrect Cleaning incorrect Maintenance	Operator Training Standardised Maintenance Protocol	5	Visual inspection	2	30

	contaminants or residue										
9	Check Extrusion Drum for moisture	Extrusion Drum Moist	Product Quality	Product Contamination Equipment damage	3	Incorrect Cleaning incorrect Maintenance	Operator Training Standardised Maintenance Protocol	5	Visual inspection	2	30
10	Ensure Extrusion Drum grounding cable is secure	Grounding Cable Damaged	Process Safety	Product Ignition Electro Static Discharge Equipment Damage	5	Incorrect Cleaning Incorrect Operation incorrect Maintenance	Operator Training Standardised Maintenance Protocol	3	Visual inspection Maintenance Checks	3	45
		Grounding Cable not present	Process Safety	Product Ignition Electro Static Discharge Equipment Damage	5	Incorrect Cleaning Incorrect Operation incorrect Maintenance	Operator Training Standardised Maintenance Protocol	3	Visual inspection Maintenance Checks	1	15
11	Inspect for Extruder Screw Ram scoring, residue, or wear	Extruder Screw Ram Damaged	Product Quality	Material stuck in non finished surface Product outside of tolerance future material contamination	5	Machine Fatigue insufficient Maintenance	Operator Training Standardised Maintenance Protocol Standardised inspection	3	Visual inspection Maintenance Checks	3	45
12	Verify Screw Ram seal integrity	Screw Ram Seal Damaged	Product Quality	Material escaping press Excessive material to clean Screw Ram Jamming	3	Incorrect Cleaning Incorrect Operation incorrect Maintenance Machine Fatigue	Operator Training Standardised Maintenance Protocol Standardised inspection	2	Visual inspection Maintenance Checks	3	18
		Screw Ram Seal not present	Product Quality	Material escaping press Excessive material to clean Screw Ram Jamming	5	Incorrect Maintenance	Standardised Maintenance Protocol Standardised inspection	1	breakdown Inspection	5	25

13	Lubricate with approved dry film lubricant	not Lubricated	Process Safety	Excessive fatigue on Screw Ram Seal Scoring of Screw Ram Material Contamination	5	Incorrect Cleaning Incorrect Operation incorrect Maintenance Machine Fatigue	Standardised Maintenance Protocol Standardised inspection	4	Visual inspection Maintenance Checks	1	20
		Too much Lubricant	Product Quality	Material Contamination	4	Incorrect Cleaning Incorrect Operation incorrect Maintenance Machine Fatigue	Standardised Maintenance Protocol Standardised inspection	4	Visual inspection Maintenance Checks	3	48
14	Perform dry test spin	Screw Ram Does not Move	Process Safety	No Process Function Excessive pressure build up Machinery Damage	5	Incorrect operation Incorrect Maintenance Machine Fatigue	Standardised Maintenance Protocol Standardised inspection operator training	4	Visual Inspection building start up test operation Maintenance Checks	1	20
		Screw Ram moves too Quickly	Process Safety	Incorrect Process Function Excessive pressure loss Machinery Damage	4	Incorrect operation Incorrect Maintenance	Standardised Maintenance Protocol Standardised inspection operator training	4	Visual Inspection building start up test operation Maintenance Checks	2	32
		Screw Ram Moves too Slow	Process Safety	Incorrect Process Function Excessive pressure build up Machinery Damage	4	Incorrect operation Incorrect Maintenance Machine Fatigue	Standardised Maintenance Protocol Standardised inspection operator training	4	Visual Inspection building start up test operation Maintenance Checks	2	32
15	Check load sensors	Load Sensors Non functional	Process Safety	Incorrect Load recorded material Flow not logged	3	Incorrect Maintenance Incorrect Cleaning	Standardised Maintenance Protocol Standardised inspection operator training	3	Visual Inspection building start up test operation Maintenance Checks	2	18
		Load sensors reading incorrectly	Process Safety	Incorrect Load recorded material Flow not logged	3	Incorrect Maintenance Incorrect Cleaning	Standardised Maintenance Protocol Standardised inspection operator training	3	Visual Inspection building start up test operation Maintenance Checks	1	9

16	Inspect die for cracks, wear, clogging	Die Damaged	Product Quality	Incorrect Product Dimension Material Lodged in Die Face	3	Machine Fatigue Incorrect Maintenance Incorrect cleaning Incorrect Operation Incorrect material used	Standardised Maintenance Protocol Standardised inspection operator training	3	Visual Inspection building start up test operation Maintenance Checks	1	9
17	Clean die with soft brush and solvent	Die not clean	Product Quality	Contamination of output product	4	Incorrect Maintenance Incorrect Cleaning Incorrect Material used	Standardised Maintenance Protocol Standardised inspection operator training Standardised Closed Down and Start Up procedure	4	Visual Inspection building start up test operation Maintenance Checks	1	16
18	Verify temperature control	Temperature control not reading correctly	Process Safety	Max Temperature Exceeded minimum Temperature not met	5	Incorrect operation Incorrect Maintenance Machine Fatigue	Standardised Maintenance Protocol Standardised inspection operator training	2	Visual Inspection building start up test operation Maintenance Checks	3	30
		Temperature control Non functional	Process Safety	Max Temperature Exceeded minimum Temperature not met	5	Incorrect operation Incorrect Maintenance Machine Fatigue	Standardised Maintenance Protocol Standardised inspection operator training	2	Visual Inspection building start up test operation Maintenance Checks	3	30
19	Inspect cutter blade for damage	Cutter blade damaged	Product Quality	Incorrect Product Dimension Material Lodged in blade	3	Machine Fatigue Incorrect Maintenance Incorrect cleaning Incorrect Operation Incorrect material used	Standardised Maintenance Protocol Standardised inspection operator training	4	Visual Inspection building start up test operation Maintenance Checks	1	12
20	Test blade movement with dry cycle	Cutter Doesn't function	Process Safety	Process Non functional	5	Incorrect operation Incorrect Maintenance Machine Fatigue	Standardised Maintenance Protocol Standardised inspection operator training	4	Visual Inspection building start up test operation Maintenance Checks	1	20
		Cutter Moves too quickly	Product Quality	Material Underdrawn	3	Incorrect operation Incorrect Maintenance Machine Fatigue	Standardised Maintenance Protocol Standardised inspection operator training	4	Visual Inspection building start up test operation Maintenance Checks	2	24

		cutter moves too slow	Product Quality	Material Overdrawn	3	Incorrect operation Incorrect Maintenance Machine Fatigue	Standardised Maintenance Protocol Standardised inspection operator training	4	Visual Inspection building start up test operation Maintenance Checks	2	24
21	Clean surface of conveyor	surface not clean	Product Quality	Product Contaminated Excessive Belt Degrading	4	Incorrect Maintenance Incorrect cleaning Incorrect Operation Incorrect material used	Standardised Maintenance Protocol Standardised inspection operator training Standardised Closed Down and Start Up procedure	5	Visual Inspection building start up test operation Maintenance Checks	1	20
22	Inspect rollers	rollers damaged	Process Safety	Belt Non Functional	4	Incorrect Maintenance Incorrect cleaning Incorrect Operation Incorrect material used	Standardised Maintenance Protocol Standardised inspection operator training Standardised Closed Down and Start Up procedure	4	Visual Inspection building start up test operation Maintenance Checks	2	32
		Rollers not present	Process Safety	Belt Non Functional	4	Incorrect Maintenance Incorrect Operation	Standardised Maintenance Protocol Standardised inspection operator training	2	Visual Inspection building start up test operation Maintenance Checks	1	8
23	Test emergency stops	Emergency stop non functional	Process Safety	No instant shut down capability	5	Power Failure Incorrect Maintenance Incorrect Operation	Standardised Maintenance Protocol Standardised inspection operator training Electricity back up system	3	Visual Inspection building start up test operation Maintenance Checks	1	15
24	Move PE-8 into bay in approved quantity	Incorrect Energetic Supplied	Product Quality	Ignition of Energetic in process Contamination of process	5	Supplier Error incorrect marking operator Error Supply chain breakdown	Operator Training Supplier Audit	2	Visual inspection Material Transport container marking	1	10
		Incorrect Quantity transported	Process Safety	Ignition of Energetic in process Over spill of material Excessive Material remaining	5	Operator Error	Operator Training	4	Visual inspection Material Transport container marking Scale Weighing	1	20

		Not transported correctly	Process Safety	Ignition of Energetic Injury of operators product contamination	5	Operator Error	Operator Training	4	Visual inspection Material Transport container marking	1	20
25	Acclimate material to room temperature	Material Not acclimatised	Product Quality	Product out of specification damage to Process	3	Operator Error	Operator Training Building maintenance	4	Fixed Acclimatisation timer Surface thermometer	3	36
26	Portion feed into sealed hopper	Material Not portioned correctly	Process Safety	Material Overspill Damage of Machinery	5	Operator Error	Operator Training	3	Visual Inspection	1	15
27	Retire to Control room	personel left in Process building	Process Safety	Personel injured	4	personell not leaving control room poor communication	Operator Training Lone working prohibition	4	Building Clearance check	1	16
28	Start extrusion cycle	Extrusion Cycle does not start	Process Safety	Mateiral built up in hopper No Product	4	Operator Error Incorrect Maintenance Machine Fatigue Part Failure	Standardised Maintenance Protocol Standardised inspection operator training Electricity back up system	2	Visual Inspection Pressure Gauges on/off system light	1	8
29	Monitor Screw Ram pressure	Screw Ram pressure increases	Process Safety	Damage to Screw Ram Spill of material	3	Operator Error Incorrect Maintenance Machine Fatigue Part Failure	Standardised Maintenance Protocol Standardised inspection operator training Pressure monitoring System	4	Visual Inspection Pressure Gauges	1	12
		Screw Ram Pressure Decreases	Process Safety	Build up of material Hydraulic fluid Spill	3	Operator Error Incorrect Maintenance Machine Fatigue Part Failure	Standardised Maintenance Protocol Standardised inspection operator training Pressure monitoring System	4	Visual Inspection Pressure Gauges	1	12

		Screw Ram has no pressure	Process Safety	No process function	4	Operator Error Incorrect Maintenance Machine Fatigue Part Failure	Standardised Maintenance Protocol Standardised inspection operator training Pressure monitoring System	2	Visual Inspection Pressure Gauges	1	8
30	Check material flow at die face	No material flow	Process Safety	Material Build Up No Material in Process	3	Operator Error Incorrect Maintenance Machine Fatigue Incorrect Material used	Standardised Maintenance Protocol Standardised inspection operator training Pressure monitoring System	3	Visual Inspection Pressure Gauges	1	9
		Excessive material flow	Product Quality	Material Build Up Product Splaying	3	Operator Error Incorrect Maintenance Machine Fatigue Incorrect Material used	Standardised Maintenance Protocol Standardised inspection operator training Pressure monitoring System	3	Visual Inspection	2	18
		Low Material Flow	Product Quality	Material out of spec Material build up	3	Operator Error Incorrect Maintenance Machine Fatigue Incorrect Material used	Standardised Maintenance Protocol Standardised inspection operator training Pressure monitoring System	3	Visual Inspection Pressure Gauges	1	9
31	Check uniformity of extrudate	Extrudate splaying	Product Quality	Material out of Spec	2	Operator Error Incorrect Maintenance Machine Fatigue Incorrect Material used Excessive material in process	Standardised Maintenance Protocol Standardised inspection operator training	4	Visual Inspection	2	16

		Extrudate not filling die	Product Quality	Material out of Spec	2	Operator Error Incorrect Maintenance Machine Fatigue Incorrect Material used Insufficient material in process	Standardised Maintenance Protocol Standardised inspection operator training	2	Visual Inspection	2	8
		no extrudate	Process Safety	Material out of Spec	2	Operator Error Incorrect Maintenance Machine Fatigue Incorrect Material used Insufficient material in process	Standardised Maintenance Protocol Standardised inspection operator training	3	Visual Inspection	2	12
32	Inspect for voids or discoloration	Voids present	Product Quality	Material out of Spec	4	Operator Error Incorrect Maintenance Incorrect Material used Insufficient material in process	Standardised Maintenance Protocol Standardised inspection operator training Material Supplier Audit	3	X-ray Visual Inspection	2	24
		Discoloration present	Product Quality	Material out of Spec Contaminated material	4	Incorrect Cleaning Incorrect Material used	Standardised Maintenance Protocol Standardised inspection operator training Material Supplier Audit Standardised Cleaning Process	3	Visual inspection	2	24
33	Run out residual PE-8	Residual PE-8 not completely removed	Process Safety	Contamination of future batches ignition of material	4	Operator error	Operator Training Standardised Cleaning Process	4	Visual inspection Regular Maintenance Checks	2	32
34	Reset Interlocks	Interlocks not reset	Process Safety	Process left in unsafe manner Injury to operator	5	operator error Incorrect Maintenance	Standardised Maintenance Protocol Standardised inspection operator training	4	Visual inspection Regular Maintenance Checks	1	20
		interlocks partially reset	Process Safety	Process left in unsafe manner Injury to operator	5	operator error Incorrect Maintenance	Standardised Maintenance Protocol Standardised	4	Visual inspection Regular Maintenance Checks	1	20

							inspection operator training				
35	Clean storage drum (wipe)	Cleaning insufficient	Product Quality	Process left in unsafe state Damage to process equipment Contaminatio n of future product	3	operator error Incorrect Maintenance Insufficient cleaning	Standardised inspection operator training Standardised Cleaning Process	2	Visual inspection Regular Maintenance Checks	1	6
36	clean Screw Ram with non-metallic scraper	Screw Ram Not Clean	Product Quality	Process left in unsafe state Damage to process equipment Contaminatio n of future product	3	operator error Incorrect Maintenance Insufficient cleaning	Standardised inspection operator training Standardised Cleaning Process	2	Visual inspection Regular Maintenance Checks	1	6
37	Clean Die	Die not clean	Product Quality	Process left in unsafe state Damage to process equipment Contaminatio n of future product	3	operator error Incorrect Maintenance Insufficient cleaning	Standardised inspection operator training Standardised Cleaning Process	3	Visual inspection Regular Maintenance Checks	1	9
38	Clean Cutter	Cutter not clean	Product Quality	Process left in unsafe state Damage to process equipment Contaminatio n of future product	3	operator error Incorrect Maintenance Insufficient cleaning	Standardised inspection operator training Standardised Cleaning Process	2	Visual inspection Regular Maintenance Checks	1	6
39	Wipe conveyor with anti-	Conveyor not clean	Product Quality	Process left in unsafe state Damage to process	3	operator error Incorrect Maintenance Insufficient cleaning	Standardised inspection operator training Standardised Cleaning Process	2	Visual inspection Regular Maintenance Checks	1	6

	static cleaner			equipment Contamination of future product							
40	Complete cleaning and inspection log	Log not filled in	Process Safety	Incorrect process control Limited Accountability batching Void	2	Operator Error Log not available	Operator Training supervisor inspection	4	Supervisory spot check	3	24
		Log filled in incorrectly	Process Safety	Incorrect process control Limited Accountability batching Void	2	Operator Error Log not available	Operator Training supervisor inspection	4	Supervisory spot check	4	32
41	Power down PLCs and lockout extruder	PLC not powered down	Process Safety	Process left in unsafe manner	4	Electrical Failure operator Error	Electrical Backup operator Training Standardised Maintenance	2		1	8
42	lockout extruder	Extruder not locked out	Process Safety	Process left in unsafe manner Injury to operator	5	Electrical Failure operator Error	operator Training Standardised Maintenance	2	inspection Key Press Log book	1	10

1. Appendix 3 – PCP

Operation Number	Operation Description	Machine, Device, Jig, Tool	Characteristic to be controlled		Control Class	Control Method							Reaction Plan if Control Method fails
			Product Characteristic	Process Parameter		Element Evaluated / Measured	Specification / Tolerance	Evaluation / Measurement Technique	Sample		Record	Assurance of Control (Incl. Procedure)	
									Size	Frequency			
PE-8 Extrusion													

1	Verify access control to extrusion bay	Key press and door locks	Controlled access	Physical key control	CT S	Key log and physical key access	Only authorised key holders	Visual + logbook check	1	Daily start-up	Access Log	Key control check	Report breach; restrict area access
2	Check ESD flooring	ESD flooring	Static dissipation	Surface resistance	CT S	Floor resistance	<10 ⁹ ohms	ESD resistance meter	1	Weekly	ESD Log	Surface resistance check	Repair/re place flooring
3	Ensure blast shields and interlocks are engaged	Interlock switch, shield	Operator protection	Circuit status	CT S	Shield and switch function	Active / engaged	Visual + system check	1	Per shift	Safety Log	Inspection	Stop work; report issue
4	Confirm area is clean and free of foreign objects	Work area	Cleanlines	Foreign object detection	CT Q & CT S	Work area cleanlines	No foreign objects	Visual inspection	1	Pre-shift	Housekeeping Log	Inspection	Clean and recheck
5	Energize control panels and PLCs	PLC, Control Panel	System readiness	Power on state	CT S	System indicators	No faults; powered on	Visual check + self-test	1	Start-up	System Log	Startup check	Notify maintenance
6	Verify fire suppression system status	Fire Suppression Panel, Suppression lines	N/A	System Armed & Functional	CT S	Panel Status Light, Visual Line Integrity	Active + No Leaks	Visual Inspection	1	Daily Start-Up	Pre-Start Checklist	System check	Halt Operations; notify safety lead
7	Test interlocks and emergency stop	Interlock switch, shield	Operator protection	Circuit status	CT S	Shield and switch function	Active / engaged	Visual + system check	1	Per shift	Safety Log	Inspection	Stop work; report issue
8	Inspect Extrusion Hopper for contaminants or residue	Extrusion Drum	Cleanlines	N/A	CT Q & CT S	Inner Drum Surface	No Visible residue	Visual Inspection	1	pre-shift	Cleaning log	inspection	Clean drum again; report repeated build up

9	Check Extrusion Hopper for moisture	Extrusion Drum	Dryness	N/A	CT Q & CT S	Inner Drum Surface	No Moisture Present	Lint-free Wipe test	1	pre-shift	Cleaning log	inspection	Dry drum; check temperature and humidity in building is correct
10	Ensure Extrusion Hopper grounding cable is secure	Grounding Cable and clamp	N/A	Electrical Continuity	CT S	Clamp Connection and condition	No Damage	Visual Inspection	1	Pre-shift	Pre-Start Checklist	Continuity check	Replace cable/clamp; reverify before proceeding
11	Inspect for Extruder Screw Ram scoring, residue, or wear	Extruder Screw Ram	Mechanical Integrity	N/A	CT Q & CT S	Ram surface	No scoring/residue	Visual Inspection	1	Pre-shift	Maintenance Checklist	Inspection	Replace or escalate for review
12	Verify Screw Ram seal integrity	Ram seal housing	Seal condition	Compression fit	CT Q & CT S	Seal contact area	No leaks or looseness	Visual inspection	1	Weekly	Maintenance Log	Inspection	Replace seal; delay operations
13	Lubricate with approved dry film lubricant	Lubricant Dispenser	N/A	Application of lubricant	CT S	Ram lubrication status	Even coating, no excess	Visual + touch test	1	Pre-shift	Lubrication Log	Lubrication	Clean and reapply approved lubricant
14	Perform dry test spin	Extruder Assembly	N/A	Rotational Function	CT S	Rotation noise/speed	Smooth operation	Manual test spin	1	Pre-shift	Test Log	Dry test	Inspect drive and bearings
15	Check load sensors	Load cell	Sensor accuracy	Calibration output	CT S	Sensor readout	Within calibrated range	Digital display reading	1	Monthly	Calibration Record	Sensor check	Recalibrate or replace
16	Inspect die for cracks, wear, clogging	Extruder Die	Structural integrity	Damage or obstruction	CT Q & CT S	Die face and openings	No visible cracks or clog	Visual + magnifier	1	Pre-shift	Inspection Log	Inspection	Replace die if damaged

17	Clean die with soft brush and solvent	Soft brush + approved solvent	Cleanlines	Surface residue	CT Q	Die face	Residue-free	Manual clean + wipe test	1	Per use	Cleaning Log	Cleaning	Repeat cleaning
18	Verify temperature control	Heater System + Thermocouple	N/A	Temp within safe range	CT Q & CT S	Temp at die head	60–70°C	Thermocouple sensor readout	1	Hourly during op	Batch Record	Temperature monitoring	Stop process; check heating element
19	Inspect cutter blade for damage	Cutter Blade	Blade integrity	Edge condition	CT Q	Blade edge	No chips or bends	Visual inspection	1	Pre-shift	Maintenance Log	Inspection	Replace blade
22	Inspect rollers	Feed Rollers	Surface integrity	Roller wear/residue	CT S	Roller surface	No cracks/residue/wear	Visual inspection	2	Pre-shift	Maintenance Log	Inspection	Replace or clean rollers
21	Clean surface of conveyor	Conveyor Surface	Cleanlines	Debris on belt	CT Q & CT S	Surface of conveyor	No residue	Wipe and visual	1	Pre-shift	Cleaning Log	Cleaning	Clean again; escalate if persistent
22	Inspect rollers	Conveyor rollers	Wear and function	Roller spin and surface	CT S	Roller surface	No cracks/wear	Visual and manual spin	2	Weekly	Maintenance Log	Inspection	Replace rollers
23	Test emergency stops	E-stop Buttons	Emergency readiness	Circuit cut	CT S	E-stop function	Immediate system halt	Press test	1	Weekly	Safety Log	Functional test	Repair before use
24	Move PE-8 into bay in approved quantity	Handling tray	Material quantity	Batch size	CT S	Weighed quantity	Per SOP allowance	Scale check	1	Per batch	Batch Record	Weighing	Adjust to approved quantity
25	Acclimate material to room temperature	Material Staging Tray	Temperature compliance	Material Temp	CT Q & CT S	PE-8 surface temp	20–25°C	Contact thermometer	3	Per batch	Batch Prep Log	Temperature check	Delay loading until in range

26	Portion feed into sealed hopper	Sealed Hopper	Loading accuracy	Feed quantity	CT Q & CT S	Visual portioning	Even distribution	Scoop + visual	1	Per batch	Batch Prep Log	Loading	Reportion material
27	Retire to Control room	Control Room	Operator safety	Distance from bay	CT S	Operator location	Outside bay	Visual confirmati on	1	Per batch	Operation Log	Personnel check	Delay until all clear
28	Start extrusion cycle	Extruder Controls	Start sequence	Initiation signal	CT Q & CT S	Start indicator	Cycle initiated	Press + visual confirmati on	1	Per batch	Batch Record	Start confirmati on	Reattempt after checks
29	Monitor Screw Ram pressure	Pressure gauge	Pressure within limits	Ram output force	CT Q & CT S	Live readout	Within operating range	Digital gauge	Continu ous	During op	Batch Record	Monitoring	Stop process if out of range
30	Check material flow at die face	Extruder Die	Flow consistenc y	Die face output	CT Q	Visual flow	Smooth and continuous	Visual inspection	Continu ous	During op	Operator Log	Visual	Adjust settings
31	Check uniformit y of extrudate	Extrudate line	Shape and size	Uniformity	CT Q	Pellet shape/dia meter	Consistent size	Visual + caliper	5	Hourly	QA Log	Visual & measurem ent	Adjust die or process
32	Inspect for voids or discolora tion	Extrudate	Product quality	Appearan ce	CT Q	Surface of pellets	No voids/discolora tion	Visual	5	Hourly	QA Log	Inspection	Quarantin e and investigat e
33	Run out residual PE-8	Extrusion Line	Product purity	Absence of prior batch mix	CT S	Extrudate appearanc e	Clear change	Visual observati on	Continu ous	Start of batch	Batch Record	Visual clearance	Discard first run; monitor contaмина tion
34	Reset Interlock s	Control System	System readiness	Interlock position	CT S	System signal	Ready/armed	System reset	1	Post-batch	Log Sheet	Reset check	Report malfuncio n

35	Clean storage drum (wipe)	Storage Drum	Cleanlines s	Surface residue	CT S	Internal drum	Residue-free	Lint-free wipe	1	Post-batch	Cleaning Log	Wiping	Repeat cleaning
36	clean Screw Ram with non-metallic scraper	Ram body	Surface cleanlines s	Powder adherence	CT S	Ram surface	Residue-free	Scrape and wipe	1	Post-batch	Cleaning Log	Cleaning	Repeat cleaning
37	Clean Die	Die tool	No build-up	Residual clog	CT S	Die face	Clear	Brush + solvent	1	Post-batch	Cleaning Log	Cleaning	Repeat cleaning
38	Clean Cutter	Cutter assembly	No residue	Blade and housing	CT S	Cutter area	Residue-free	Wipe + inspect	1	Post-batch	Cleaning Log	Cleaning	Repeat cleaning
39	Wipe conveyor with anti-static cleaner	Conveyor surface	ESD compliance	Surface cleanlines s	CT S	Conveyor belt	Clean and dry	Wipe with cleaner	1	Post-batch	Cleaning Log	Cleaning	Repeat wipe
40	Complete cleaning and inspection log	N/A	N/A	Documentation	CT Q & CT S	Log filled and signed	100% completed	Visual check of log	1	Pre-shift	Cleaning Log	Documentation	Retrain operator; escalate if incomplete
41	Power down PLCs and lockout extruder	PLC system	Shutdown sequence	Control power state	CT S	PLC indicators	No power	Power down + lockout tag	1	Post-batch	Shutdown Log	Power check	Delay until confirmed
42	lockout extruder	Extruder	Safe isolation	Lockout tag status	CT S	Lockout applied	Visible + verified	Tag + checklist	1	Post-batch	Shutdown Log	Lockout	Stop work if not locked

