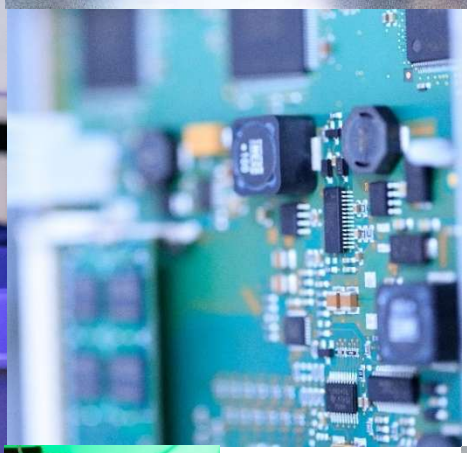
smiths detection



GLOBAL SUPPLIER QUALITY MANUAL

EDITION 2024

PREFACE

Smiths Detection is a global leader in threat detection and screening technologies. We take pride in our commitment to make the world a safer place. Our goal is simple – to provide the security, peace of mind and freedom of movement upon which the world depends.

With a strong presence in four main market segments, Aviation, Ports & Borders, Urban Security and Defence, Smiths Detection is dedicated to pushing the boundaries of innovation while offering best-in-class quality products and services to our customers. Our strong market position is determined by the quality and reliability of our products and services. Therefore, we partner with world class suppliers and set high expectations for them in terms of product quality, on-time delivery, cost leadership as well as health, safety, environment sustainability, ethical and legal and regulatory compliance management.

Smiths Detection's success for our customers depends on our suppliers. Based on that, the purpose of this manual is to provide a comprehensive and standardized guide for our suppliers on the requirements and expectations we have of them. We are dedicated, including through this manual, to building strong relationships with our suppliers fostered by clear communication, a clear understanding of our mutual expectations and responsibilities, trust, and commitment.

Nicola Molloy

Procurement Director

Paul Gale

Quality Director

smiths detection

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1. Introduction

1.1. Purpose

This Supplier Quality Manual ("SQM" or "Manual") defines expectations and requirements for all suppliers that deliver products and/or services ("Supplies") to Smiths Detection or its customers ("Suppliers"). These expectations supplement the terms and conditions (T&Cs) of purchase. The latest version of this Manual is available for download on the Smiths Detection Internet site under the following link: www.smithsdetection.com/suppliers

The Supplier shall meet or exceed the requirements and guidelines defined in this Manual for as long as it provides products and/or services ("Supplies") to Smiths Detection and its customers. Compliance with this Manual, Smiths Detections' expectations and the requirements identified in this Manual does not, however, absolve Supplier of or release Supplier from Supplier's statutory, contractual and legal responsibilities and obligations in connection with Supplier's (a) development and/or delivery of product(s) to Smiths Detection and its customers, and/or (b) performance of services for Smiths Detection and its customers.

Suggestions for improving the content of this document are welcome and can be sent to globalIBMS@smithsdetection.com

1.2. Scope

Requirements specified in this Manual apply to all Suppliers that develop and produce Supplies such as original equipment (OE), parts, software and other products such as chemicals, and services that are sold, directly or indirectly, to Smiths Detection. They are also applicable to Smiths Detection direct-to-customer Suppliers that are contracted by Smiths Detection. It is the responsibility of each Supplier that provides Supplies directly to Smiths Detection or its customers to cascade the requirements of this Manual to their supply chain, including all sub-tier Suppliers and distributors, and ensure their compliance. Requirements specified in this Manual do not apply to non-production related Suppliers.

This Manual does not limit any of the rights or remedies of Smiths Detection under any Non-Disclosure Agreement (NDA), other supply contracts, or T&Cs between Smiths Detection and the Supplier.

This Manual is provided in English. Only the English version is a controlled document in compliance with Smiths Detection document control procedure. Translations of this document in other languages may be provided but are meant only for information and do not have precedence.

1.3. Terms and Definitions

Term	Definition
5S	A standardized five-step process for maintaining an organized, safe, clean and efficient workplace: sort, set in order, shine, standardize, and sustain.
8D	The eight disciplines problem-solving process
FAI	First Article Inspection
FIFO	First In First Out
FMEA	Failure Mode and Effects Analysis
Gauge R&R	Gauge Repeatability and Reproducibility
KPI	Key Performance Indicators
MRB	Management Review Board

NDA	Non-disclosure Agreement
PLP	Product Lifecycle Process
PQP	Product Qualification Process
QMS	Quality Management System
RPN	Risk Priority Number
RFQ	Request For Quotation
Supplier	Any entity supplying parts, materials, software or services to Smiths Detection
SQIP	Supplier Quality Improvement Programme
T&Cs	Terms and Conditions

2. General Requirements

2.1. Business Language

All communications between Smiths Detection and its Suppliers shall be conducted in English, unless explicitly specified by the Smiths Detection entity contracting for the Supplies. All documents, including Product Qualification Process (PQP), shall be submitted in English, unless otherwise specified by Smiths Detection. Additionally, if common to both parties, documents may display the native language of the Supplier or the contracting Smiths Detection entity alongside the English version.

2.2. Quality Management System

An effective Quality Management System (QMS), satisfying ISO 9001 requirements, is a mandatory requirement of Smiths Detection for its Suppliers. A Supplier's ISO 9001 certification shall be made available to Smiths Detection upon request. The Supplier's QMS effectiveness shall be demonstrated through the following key aspects:

- Product Quality and Safety: Ensuring that products meet the specified quality standards and consistently satisfy Smiths Detection and its customer requirements.
- Delivery Quality: Consistently delivering products and services on time and in compliance with agreed-upon specifications.
- Effective Implementation of Corrective Actions: Swiftly addressing and resolving quality and delivery issues by implementing appropriate corrective actions.
- Continuous Improvement: Continuously improving processes and products to enhance overall performance.
- Project Delivery: Ensuring the successful and timely implementation of projects in line with Smiths Detection and its customer expectations and requirements.
- Effective communication: Maintaining open and clear communication both internally within the organization and with Smiths Detection to ensure a smooth flow of information.

The Supplier shall maintain a valid ISO 9001 certification, or another equivalent accreditation accepted by Smiths Detection to conduct business with the company. This certification requirement may be waived by Smiths Detection in limited circumstances at its sole discretion. The Supplier shall promptly inform Smiths Detection if and upon becoming aware that any such certification is revoked, suspended, expired, or if they encounter unresolvable challenges in renewing it. If no renewal of the certification is planned, the Supplier shall inform Smiths Detection in writing at least 3 months prior to the expiration date.

2.3. Regulatory and Statutory Compliance

Suppliers shall adhere to all relevant laws and regulations applicable to their furnishing of Supplies to Smiths Detection and commit their suppliers throughout their supply chain for Smiths Detection to do the same. This compliance shall be implemented during the project development phase and verified through the Product Qualification Process (PQP) submission.

2.4. Corporate Social Responsibility

Smiths Detection holds strong principles regarding business ethics, employee working conditions, human rights, and environmental leadership. Therefore, it is required that its Suppliers certify they will honour Smiths Supplier Code of Conduct in the way they conduct their business. Smiths Detection Supplier Code of Conduct is available for download on the Smiths Detection Internet site: www.smithsdetection.com/suppliers

Suppliers shall provide certification and/or evidence of their honouring of the Supplier Code of Conduct upon Smiths Detection's written request. Smiths Detection may also conduct audits after prior written

notification or make inquiries to assess this compliance of the Supplier. The Supplier shall cooperate with any such audits or inquiries.

2.5. Environment

Smiths Detection upholds a strong commitment to environmental protection, and all Smiths Detection sites hold ISO 14001 certification. All Suppliers are encouraged to obtain ISO 14001 certification. Effective environmental management is a fundamental requirement for engaging in a business relationship with Smiths Detection. As part of the initial assessment and before awarding any business, Suppliers are typically evaluated on their environmental management system. This management system shall ensure compliance with relevant environmental regulations including the "Control of Prohibited and Regulated Substances" where relevant and shall encourage continuous improvement in controlling environmental aspects.

Upon request, Suppliers are required to provide their recycling and disposal procedures concerning their product. Additional data may be required such as energy consumption and emissions data for the Life Cycle assessment of Smiths Detection products. The Supplier shall make its best efforts to provide this data to Smiths Detection as available.

2.6. Audits and Right of Access

Smiths Detection reserves the right to access the Supplier's or their sub-tier Supplier's facility for the purpose of validating the Supplier's and sub-tier Supplier's Quality Management System applicable to their Supplies for Smiths Detection at any stage of the Product Life Cycle. Additionally, it may also be requested by Smiths Detection to carry-out these assessments with its customer or with/via a third party. The scope of validation may be extended to other applicable aspects such as Information Security, Environmental Control, Corporate Social Responsibility, and any other areas covered by this Manual, the T&Cs or otherwise relevant to the business relationship between Smiths Detection and the Supplier.

Given the nature of its products, Smiths Detection Suppliers may be required to host Government Representatives' visits and assessments. Suppliers shall provide the necessary access to their sites and facilitate the intended assessment by the Government Representatives.

2.7. Information Security

Smiths Detection places a paramount emphasis on Information Security. Suppliers must comply with regulatory requirements and contractual T&Cs for Information Security, data protection and privacy. Additionally, the company strongly encourages its Suppliers to align with internationally recognized standards, such as ISO 27001, to ensure robust information and cyber security practices. These requirements, standards and practices include but are not limited to the following:

- Protection of confidentiality through Non-disclosure agreements (NDAs) or appropriate contractual provisions shall be a general component of the Supplier's contracts. Confidentiality shall be ensured with sub-tier Suppliers, service providers, customers or any other business relationship, and obligations renewed at defined intervals.
- The Supplier shall define guidelines for the exchange of information and data internally and externally, including exchange via secure media, encryption of systems, automatic classification of emails and documents via the system.
- The Supplier shall provide regular training sessions to all personnel. The level of personnel training on Information Security practices shall be checked during internal audits.
- The Supplier shall define and monitor access authorisations to their premises for personnel, providers, contractors, and visitors. Compliance with access guidelines shall be checked regularly.
- The Supplier shall maintain a tidy working environment (e.g., Clear Desk) procedure where unattended equipment, resources and information are adequately protected.

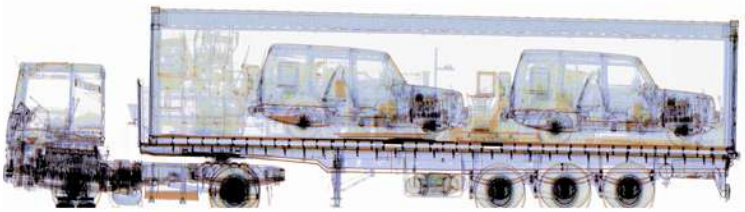
- The Supplier shall conduct regular audits to assess its compliance (a) with Information Security requirements that are mandated by law and contained in the Suppliers' contracts, and (b) against internationally recognized standards. All findings from these audits shall be addressed with a comprehensive action plan, made available to Smiths Detection on request.
- The Supplier shall employ a comprehensive procedure to identify, address, manage and resolve Information Security incidents and breaches, including root cause analysis, prompt communication, and implementation of corrective actions.
- The Supplier shall inform Smiths Detection immediately of any Information Security issues that may concern personal data, Smiths Detection data, government data, Delivery or Quality requirements.

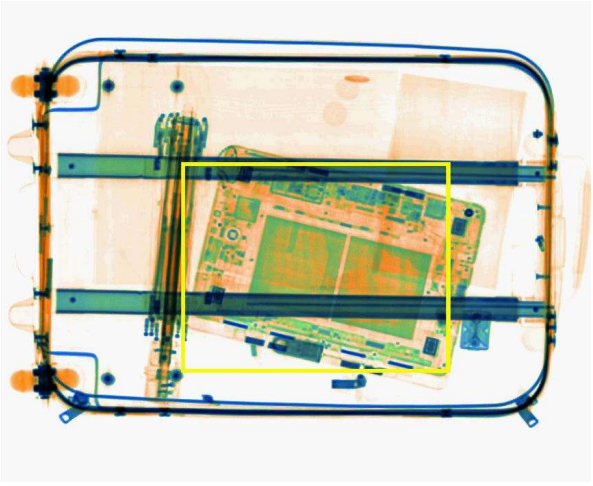
2.8. Competence & Training

Suppliers shall ensure that personnel performing work for Smiths Detection possess the necessary competence and training. The competencies and qualifications necessary shall be defined by industry standards and the Supplier. The Supplier shall ensure that training documentation is retained and shall furnish this documentation to Smiths Detection upon request.

2.9. Counterfeit Parts Prevention

Suppliers shall operate effective verification and validation processes to detect and prevent the inclusion of counterfeit or suspected counterfeit items in Supplies delivered to Smiths Detection. Suppliers should ensure that externally provided Supplies are acquired from original or authorized manufacturers, distributors, and sources. Any suspected counterfeit parts found by the Suppliers in Supplies for Smiths Detection, shall be quarantined and reported to Smiths Detection within 24 hours of Supplier's discovery.





3. Project Development and Implementation

3.1. Smiths Detection PLP

The Smiths Detection Product Life Cycle Process (PLP) is an internal vital business process designed to proactively meet regulatory requirements and reduce risks while developing complex products. It provides a structured approach to review product development progress, identify problems early, avoid wasting time, money, and effort while delivering high quality products to market. It uses a common framework and terminology across Smiths Detection sites and functions. This development process is separated into phases by gate reviews.

Supplier onboarding and qualification constitute essential components of the PLP process for every project. Hence, Smiths Detection places significant emphasis on engaging Suppliers at an early stage of the project development to facilitate product and process development and to ensure effective implementation of all regulatory and contractual customer specific requirements.

3.1.1. Early Supplier Involvement

Depending on the project requirements, Smiths Detection may need to involve their Suppliers at an early stage to carry out concurrent engineering activities. The company anticipates active participation from its Suppliers in these activities, whenever required. This process shall be thoroughly documented, encompassing all activities and the commitment to implement them, including quality, regulatory and contractual requirements.

Additionally, emphasis is placed on the importance of communicating quality, regulatory and contractual requirements to the Supplier at the early stages of the project since it is crucial for the Supplier to be fully aware of and compliant with these requirements. Smiths Detection seeks confirmation from the Supplier, demonstrating their capability to meet and implement these requirements effectively. Furthermore, the Supplier is expected to have the necessary capability to consistently comply with these requirements throughout the project's lifecycle.

3.1.2. Customer Specific Requirements

In addition to the general requirements included in this Manual, the Suppliers are expected to comply with any specific requirements of Smiths Detection's customers that have been communicated to the Suppliers on a project basis. The implementation of such requirements will be subject to an agreement between Smiths Detection and the Supplier and will be validated as part of the PQP submission.

3.2. Supplier Onboarding

Smiths Detection employs a structured approach to assess the Supplier's processes and capabilities to meet the requirements for a given project. Prior to award of any contracts, Suppliers will be evaluated based on:

- Process/technical capability
- QMS capability
- Delivery
- Cost
- Project implementation capability
- Health, Safety and Environment (HSE) status and controls
- Ethics and legal and regulatory compliance
- Information Security
- Any other requirements specified by Smiths Detection and the customer

In addition to Technology and Procurement initial assessments, a questionnaire is utilized to assess the Supplier's QMS, Project Management capabilities, Information Security, HSE status and controls, and ethics and legal and regulatory compliance. This questionnaire is developed based on lessons learned from previous projects, "Best-in-Class" practices and covers the minimum requirements to fulfil a Supplier relationship with Smiths Detection. New and potential Suppliers are expected to facilitate this initial assessment process by completing the questionnaire (i.e., self-assessment) prior to the on-site assessment and provide dedicated necessary resources for the on-site assessment.

Suppliers are required to achieve a "GREEN" result from the questionnaire assessment and achieve an acceptable score on all major parameters. If the result is "YELLOW", a steering committee will decide whether the Supplier may be selected. Furthermore, Smiths Detection may engage a third party to conduct ESG (Environmental, Social and Governance) assessments of a Supplier on its behalf as part of the onboarding process.

3.3. Approval of Special Supplier Processes

Certain manufacturing processes cannot be verified using normal monitoring and measurement techniques. These processes are classified as special processes and include, but are not limited to, heat treatment, welding, brazing, plating, painting, coating, etc. The Supplier must demonstrate the ability to control the elements of these processes to achieve the defined results. A technical assessment of the Supplier may be required in addition to the initial assessment of the Suppliers. The technical assessment evaluates the Supplier's capability to manufacture the potential product. Smiths Detection may audit pertinent processes using a specific standard such as AIAG CQI audits (Appendix 2).

3.4. Risk Assessment & Contingency Planning

The Supplier shall conduct a risk assessment of their operations that supports Smiths Detection's production facilities, quality requirements and delivery schedules for any occurrence that may interrupt those facilities. Each assessment should consider, at a minimum, the impacts arising from:

- Natural and health disasters
- Geo-political risks
- Supply chain disruptions
- Facility or system issues
- Information loss
- Legal and regulatory breaches
- Intellectual property concerns
- Personnel resources concerns
- Equipment problems

For each identified risk, the Supplier shall prepare an adequate business continuity and contingency plan to ensure continued operations for Smiths Detection. The Supplier shall provide the contingency plans to Smiths Detection when requested. The Supplier shall also communicate to Smiths Detection any critical risk scenario without a contingency plan that may result in a major disruption.

3.5. Supplier Qualification

Smiths Detection delivers the solutions needed to protect society from the threat and illegal passage of explosives, prohibited weapons, contraband, biological threats, toxic chemicals and narcotics. Our customers are relying on Smiths Detection products to save lives daily. Therefore, the highest possible quality is expected from our Suppliers while adhering to our quality standards as outlined in this Manual. All Suppliers are required to follow a structured approach to product and process development that ensures Built-in Quality and regulatory compliance and eliminates risk of failure.

As such, all Suppliers are encouraged to follow a structured product quality planning methodology as part of a robust quality system and programme implementation. Smiths Detection approves its Suppliers using a Product Qualification Process (PQP) methodology, as defined in Appendix 3 and requires Suppliers to comply with Smiths' Detection PQP requirements. PQP is a verification method of the product and process that documents and certifies the output of the product quality planning methodology which includes a First Article Inspection (FAI). The purpose of PQP is to ensure the Supplier understands the design and specification requirements and determine if the Supplier's manufacturing process can consistently meet these requirements.

The PQP will include a set of product and process documentation agreed at the start of each project between Smiths Detection and the Supplier. The documentation will be reviewed based on the product specification by Smiths Detection before the FAI. Suppliers shall address any findings from the review until final documentation is signed-off by Smiths Detection. The PQP checklist will outline the required documentation for every PQP submission, provided on a project basis. The overall PQP submission sign-off is based upon documentation approval and a successful FAI submission. Smiths Detection reserves the right to require parts be requalified based upon process data submission on an annual basis. The following are key requirements of the Supplier qualification process and constitute essential elements of the PQP submission:

3.5.1. Process Flow Chart

The Process Flow Chart shall be submitted to Smiths Detection as part of the basic manufacturing process documentation. It serves as a reference to understand the overall process and ensure consistency in operations. It shall represent the entire process in a visual format, outlining the physical process steps and controls from incoming material to assembly, test, rework, and shipping. The Process Flow Chart shall be continuously reviewed and updated to ensure its accuracy and alignment with the actual process. Changes to the Process Flow Chart shall follow the Change Management Process detailed in this Manual (Section 5.).

3.5.2. FMEA Methodology

Suppliers shall follow the Failure Mode and Effects Analysis (FMEA) methodology similar to AIAG Potential Failure Mode & Effects Analysis Manual (Appendix 2), to examine possible risks for both product and process and their evaluation regarding severity, possibility of occurrence, and the possibility of detection. All identified risks shall be minimized by introducing appropriate actions. The FMEA is an important methodology for risk assessment and mitigation. Therefore, FMEA shall be used throughout the Product Life Cycle and as a continuous improvement tool (e.g., based on pareto Risk Priority Number (RPN) assessment, action priority review and quality concerns etc). Suppliers shall develop Process and Product FMEAs for the purpose of new product qualification, introduction of new manufacturing methods, relocation of productions, when defects occur and where required.

3.5.3. Test Planning

Suppliers shall create and execute a plan for the testing of the product based on the product specifications as part of the product qualification and to ensure that the product will continuously meet the design specification. The plan shall contain a comprehensive description of all intended tests, including the timeline, quantities etc. The test plan shall be agreed with Smiths Detection. Upon execution, the results shall be shared with Smiths Detection for evaluation. All underperformance problems shall be addressed with corrective actions.

For serial production, the Supplier shall define and document the serial production test plan. This should include test coverage (where required), test equipment, test methodology, frequency, and sample size. The test plan shall be shared with Smiths Detection for review and approval before implementation. Changes to the serial production test plan shall follow the Change Management Process detailed in this manual (Section 5.).

3.5.4. Control Plan

The Control Plan is a tool for the planning of defects prevention during production. The Control Plan shall outline the necessary actions, such as measurements, inspections, quality checks, or monitoring of process parameters, that are required at each phase of the Supplier's process to ensure that the process outputs conform to pre-determined requirements.

Suppliers shall develop their Control Plan during product and process development phases. The Control Plan shall cover pre-series production as well as series production. It shall be aligned with the Process Flow Chart and FMEA and shall take input from the result of Product and Process FMEAs, experiences and lessons learned from similar processes. It is crucial to also consider customer-specific requirements while developing the Control Plan in alignment with Smiths Detection specifications.

3.5.5. Capacity Requirements

The capacity verification process holds particular significance in several scenarios, including the introduction of new products or Suppliers, modifications in product or process, capacity expansion, production relocation, or in response to Supplier performance challenges. During the project development phase, Smiths Detection undertakes a meticulous evaluation of capacity requirements to ascertain the Supplier's ability to meet the specified volumes accurately. To ensure a comprehensive evaluation, the capacity verification encompasses all process steps, or can be limited to individual critical process steps. The capacity verification process shall be diligently documented, providing a transparent record of the evaluation as well as the identified weaknesses and corrective actions. Smiths Detection may require performing a capacity verification during project development at the Supplier location to evaluate Supplier's process capability to meet capacity requirements.

3.5.6. Release of Manufacturing Stations

All production and assembly processes shall be covered by a manufacturing release verification. Prior to the release of manufacturing stations for the start of serial production, the Supplier shall verify the below listed items:

- Capacity
- Capability study, where required
- Verification of test equipment (e.g., Gauge R&R)
- Completed and approved documents (e.g., Work Instructions, Control Plan)
- Maintenance status and plan
- Calibration status and plan
- Compliance with customer requirements, where required

Any deviations shall be documented and communicated to Smiths Detection, with corrective actions, for approval as explained in paragraph 4.6.

3.5.7. Prototypes

Prototypes are representative parts used for the verification of the design and functionalities of the Supplier's Supplies. The Supplier shall submit prototypes when required and for the purpose of design and specification assessment. Prototypes shall be clearly identified as "Prototype Part", with the Purchase Order number and sent to the address and addressee on the Purchase Order. A prototype inspection report shall be submitted with the samples and when requested. The report shall include assessments made by the Supplier such as dimensional analysis, functional testing results, performance data and any other data as requested.

3.5.8. First Article Inspection

First Article Inspection (FAI) parts are initial samples that are produced and tested under serial production conditions, including production location, raw material, assembly equipment, test equipment and packaging. These FAI parts shall be submitted to Smiths Detection receiving site in line with the agreed plan (e.g., quantities, date, documentation, packaging, test results, dimensional analysis). FAI samples shall be clearly identified as "FAI Samples" with the Purchase Order number clearly identified and sent to the address and addressee on the Purchase Order. The test results shall be documented and submitted with the FAI samples.

Where required, FAI samples shall cover different production and test configurations (e.g., mould cavities). Smiths Detection may require specific testing or assessments to be submitted with the FAI samples. A successful evaluation of the FAI samples, including fit, form and assembly test at the receiving site, is a requirement for the PQP sign-off.

3.5.9. Technical Cleanliness

In general, it is required that Suppliers maintain a clean and tidy working environment to mitigate risks of contamination to the product where required. The Suppliers shall control the cleanliness and tidiness of their production areas through robust procedures and a comprehensive 5S approach. Contamination to the product may arise from the environment (e.g., flooring, ceiling, layout plan, ventilation etc), personnel (i.e., handling), logistics (i.e., packing, transport, storage etc), and equipment (i.e., during assembly or processing). The Supplier shall assess all these sources of contamination and ensure necessary controls and actions are in place.

Technical cleanliness is a requirement for many Smiths Detection products. It plays an important role for the product reliability and where the product is sensitive to contamination in general or to some specific types of particles. Residual dirt on sensitive products can impair the otherwise high quality and even cause malfunction of the product. A "technically clean" product is generally defined by Smiths Detection as a product that has no impurities that could impair further processing or function. On a project basis, Smiths Detection will define the required level of technical cleanliness of the product. The Supplier shall implement necessary production methodologies and measures to achieve the required technical cleanliness level, and this will be subject to qualification and approval by Smiths Detection. The company may also require the Supplier to comply with a standard such as ZVEI "Technical Cleanliness in Electrical Engineering" (Appendix 1).

3.5.10. Sub-tier Supplier Management

Sub-tier Suppliers have a significant impact on the quality, delivery and cost of the final product. Therefore, it is critical for each Supplier to manage their sub-tier Suppliers properly using an effective Supplier Management System. Suppliers shall establish processes to manage their respective sub-tier Suppliers, regardless of how directed. These processes shall include:

- Selection, evaluation, and qualification of sub-tier Suppliers based on their capabilities to meet Smiths Detection's and the customer's quality, delivery, cost, service, HSE, and ethics and legal and regulatory requirements.
- Continuous monitoring of sub-tier Supplier performance and periodic auditing with subsequent corrective actions for identified gaps and non-compliance with the aforementioned requirements.

Smiths Detection and its customers require access to sub-tier Suppliers' sites and associated audit rights, so Suppliers must include terms in its agreement with sub-tier Suppliers that permit Smiths Detection and its customers a right to access and audit such sub-tier Supplier, for the purpose of verifying and validating that the sub-tier Supplier has proper controls in place for their supply chain for Smiths Detection's Supplies.

4. Serial Production Control

Upon successful PQP approval, the Supplier can proceed to serial production. Throughout this stage, Suppliers shall adhere to and comply with the specified requirements outlined in the following sections to ensure seamless operations and product quality.

4.1. Release of Products and Services

Suppliers shall verify that the product requirements have been met prior to the release of products to Smiths Detection. Product conformity and compliance shall be verified and validated against the approved Control Plan. Suppliers shall retain documented information to include evidence of conformity with acceptance criteria and traceability to the person(s) authorizing release. Documented information required to accompany the product, such as certificates of conformance, shall be defined during the project stage and shall be present when received by Smiths Detection.

4.2. Material Management

4.2.1. Inventory Management

The Supplier shall utilize an inventory management system to optimize inventory levels, reduce the risk of material shortages, reduce the risk of obsolete products, and ensure stock rotation. The First In, First Out (FIFO) approach shall be applied to maintain product usability and effective traceability.

4.2.2. Material Traceability

The Supplier shall follow a traceability method for unique identification of each part and finished material lot, as agreed upon with Smiths Detection. The traceability system shall enable the identification of raw material lots and raw material unique serial numbers where required. During project development, the Supplier shall work closely with Smiths Detection to develop and gain approval for an acceptable method, location, and content for product marking. This agreement shall be in line with the traceability method and shall not conflict with any of the raw material traceability requirements or the traceability system capabilities.

4.2.3. Material Identification

The Supplier shall implement a robust system to identify products accurately throughout the realization process. The system will include mechanisms to track the production status, verify product acceptance through inspections and testing, effectively manage product disposition and prevent product mix-up. Suppliers shall ensure that products which do not conform to their requirements are identified and controlled to prevent their unintended delivery to Smiths Detection. The Supplier is responsible for maintaining the necessary records to ensure product quality.

4.2.4. Material Handling

The Supplier shall develop and maintain an adequate plan for the proper handling, packaging, storage, protection and preservation of all products and materials. This plan shall be applied to all internal and external Supplier processes. Suitable methods shall be implemented to manage the shelf life of products, as required. Material handling, packaging, and storage procedures shall be designed to prevent contamination, damage, or degradation of products to ensure product integrity and quality. Necessary measures and methods shall be implemented as required and where material characteristics can be impacted by external factors such as Electrostatic Discharge (ESD), or particle contamination. The Supplier shall demonstrate that an ESD and particle contamination control is in place where required.

4.3. Quality Objectives

Quality objectives to meet customer requirements shall be defined, established, and reviewed throughout the organization. The review of these objectives and the performance shall be integrated into the management review process. In cases where quality issues and deviations are identified, appropriate

actions shall be taken to address them. If there are quality performance issues that have the potential to impact safety, quality or delivery, the Supplier shall promptly inform Smiths Detection. Supplier shall take appropriate action based on the nature and criticality of the non-conformity and its effects on the conformity of Smiths Detection products. Additionally, the Supplier shall establish and maintain an internal material review procedure such as Material Review Board (MRB) that facilitates the decision-making process about material quality and customer risk mitigation.

4.4. Non-Conforming Product Management

Smiths Detection categorizes non-conforming product complaints based on the source of the concern and its severity: Field Complaints, Production Complaints and Project Development Complaints. Suppliers shall follow the 8D Methodology (Appendix 2) for the root-cause analysis and resolution of all non-conforming product complaints. Smiths Detection will submit non-conforming product for assessment by the Supplier, where feasible. If destructive analysis is required, Smiths Detection shall be notified to seek approval prior to the start of testing process.

The Supplier shall implement containment actions immediately after a complaint is issued by Smiths Detection. The status of containment shall be communicated to Smiths Detection within one working day of the complaint notification. All Smiths Detection sites that are possibly affected shall be notified by the Supplier of the potential issue and the implemented containment. Impacted lots, including material in transit, shall be communicated with relevant Smiths Detection sites as part of the containment.

The Supplier shall carry-out an analysis of the root cause using appropriate problem-solving techniques such as 3x5-Why, Ishikawa, Failure Tree Analysis, Is/Is Not (Appendix 2). The detailed root-cause analysis and results shall be documented in the 8D and communicated in a timely manner and upon request to Smiths Detection.

Once the root-cause is determined, the Supplier shall define, implement, and verify Corrective Actions. Evidence of effectiveness shall be documented in the 8D. The final 8D report shall be submitted within 10 working days of the issue notification. If necessary, extensions of the 8D submission may be agreed between Smiths Detection and the Supplier. The 8D process can be closed after the approval of the final report by Smiths Detection.

After each complaint, the Supplier shall certify parts and packaging using Smiths Detection standard form SDF-07 “Identification of Certified Material after Complaint”. The clean point (i.e., first lots shipped after containment) information shall be communicated to Smiths Detection and documented in the 8D report where feasible. Material that has been subjected to 100% inspection due to complaint shall be marked. The method and type of marking and/or identification shall be agreed upon with Smiths Detection. This Certified Material process shall be maintained until permanent corrective actions have been successfully implemented.

In the event of non-conforming product being delivered to any Smiths Detection site, Smiths Detection reserves the right to seek cost recovery for the cost of the defect. These include additional handling, documentation, customer costs and penalties, time spent which includes administrative and labour, production interruptions, replacement cost, travel cost, and other associated costs to a defect delivered to a Smiths Detection site or a failure discovered in the field deemed to be caused by supplier quality.

In the case of “No Failure Found”, a joint investigation (e.g., extended testing, stress testing, etc.) shall be started between Smiths Detection and the Supplier. When required, technology and/or design teams from both Smiths Detection and the Supplier shall be involved in the investigation of the “No Failure Found” issue.

4.5. Internal Audit

The Supplier shall have a procedure and process in place to conduct regular internal audits aimed at evaluating the effectiveness of its QMS. This internal audit process shall be documented and systematically executed to ensure consistency. The findings from the internal audits shall serve as a

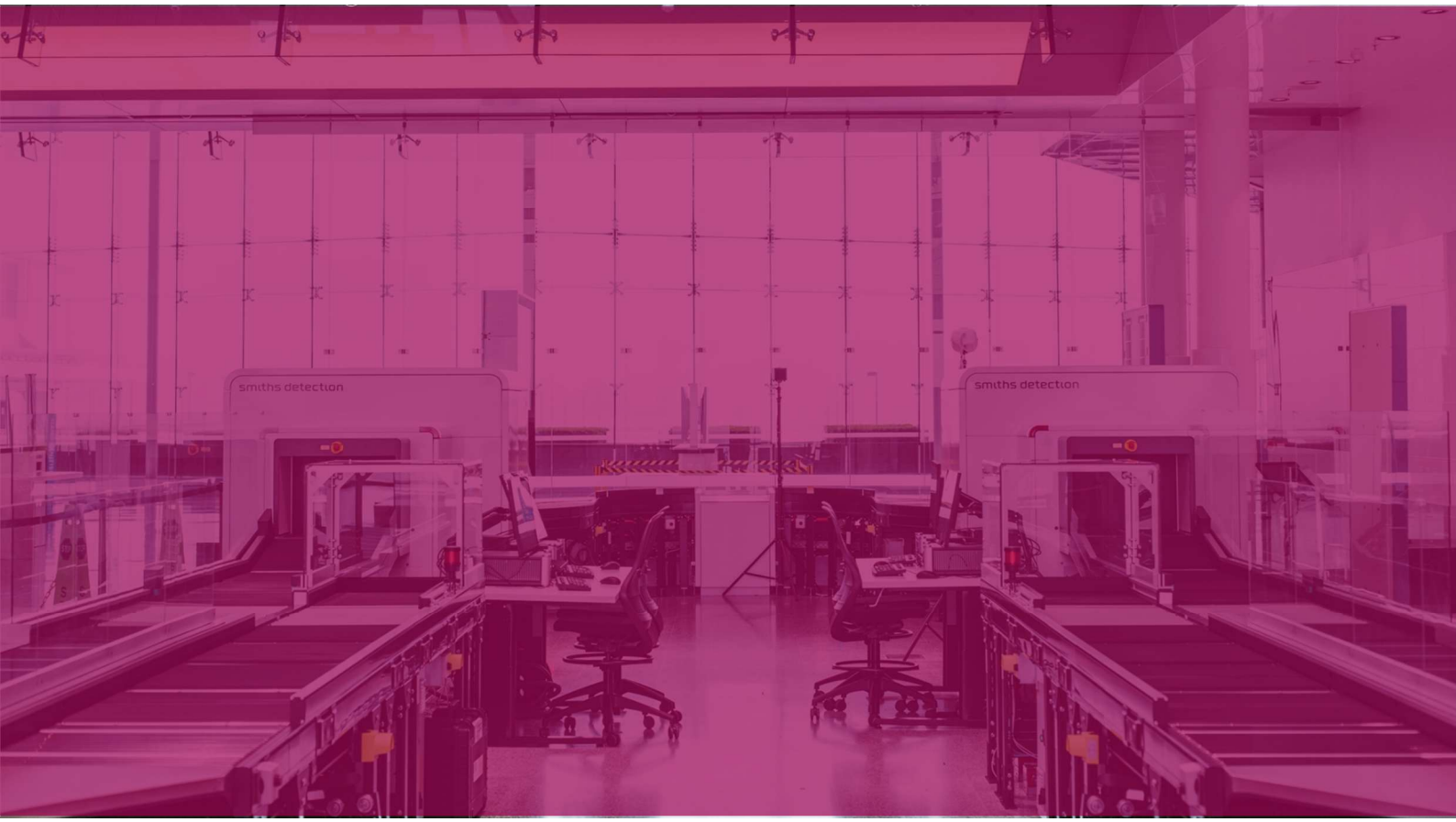
crucial input for continuous improvement efforts, enabling the Supplier to identify areas of improvement and enhance its QMS further. Any identified non-conformities shall be promptly addressed with appropriate corrective actions to rectify the root causes and prevent their recurrence.

4.6. Deviation Requests

In the event of deviation from the specification, the Supplier shall submit a deviation request to Smiths Detection for approval before delivery. The Deviation Request Form is available for download on the Smiths Detection Internet site: SDF-08 “Smiths Detection Deviation Request”. The request shall include the reason for the deviation, a comprehensive risk assessment, and the details regarding the quantity and/or duration of the deviation. Prior to shipping any material subject to deviation, written approval from Smiths Detection is mandatory. Additionally, all deliveries based on a deviation shall have additional identification labels as agreed upon with Smiths Detection. The Supplier shall be responsible for any additional documentation, testing procedure, if required, samples submitted to Smiths Detection for verification. Deviation requests are not intended to be used as long term or routine mechanisms for acceptance of nonconforming product or services from the Supplier.

4.7. Calibration of Test and Inspection Equipment

Calibration of test and inspection equipment is a critical aspect of maintaining accurate and reliable measurements in a QMS. The Supplier shall establish and implement a calibration programme (e.g., in accordance with ISO 9001) to ensure all inspection and test equipment used in their processes are regularly calibrated and maintained to ensure their continuing fitness for use. Calibration activities may be performed internally or externally, shall be traceable and adhere to recognized standards and guidelines, such as UKAS and NIST, to maintain the precision and accuracy of the equipment. Equipment out of calibration shall not be used in production to prevent potential quality issues.



5. Change Management

Smiths Detection employs a rigorous change management approach that emphasizes risk mitigation and effective communication. Suppliers shall maintain a documented process for the control and implementation of changes that impact product and manufacturing processes. The effects of changes on product quality and reliability shall be assessed, verified, and validated and documented to ensure compliance with Smiths Detection product requirements prior to implementation. All other potential risks (i.e., risk on delivery) associated with the change shall be identified and addressed as part of the change control process.

After product approval by PQP process, the Supplier shall not make any changes to the product or process without the approval of Smiths Detection. The Supplier shall notify Smiths Detection prior to any changes that affect products to obtain prior approval by the authorised Smiths Detection personnel and/or representatives. Suppliers shall submit a written request to all affected Smiths Detection sites with the following minimum information, using the Supplier Request for Change Form that is available for download on the Smiths Detection Internet site: SDF-09 "Smiths Detection Request for Change".

- Detailed description of the change
- The detailed reason for the change (e.g., continuous improvement, product reliability improvement etc)
- A comprehensive risk assessment for the intended change
- A validation plan for the change
- A timeline demonstrating proper control: the timing for assessment, approval, and implementation

The below are examples of changes requiring notification and prior written approval by Smiths Detection and where applicable, PQP re-submission:

- Loss or change in accreditation status
- Any production process change
- Drawing or specification changes
- Material changes or new material supplier
- Special process changes including heat treatment, plating, coating, etc.
- New or modified production tooling
- Re-locating equipment within a site
- Manufacturing location change
- New sub-tier Supplier or sub-tier Supplier process change
- New or modified testing and/or measuring equipment
- Packaging and/or labelling change

Smiths Detection reserves the right to reject a Supplier's request for a change when:

- Data is missing.
- Changes may affect safety and/or regulatory requirements.
- The intended changes may present a high risk for quality, reliability, cost or delivery.
- There are risks that have not been assessed and/or considered within the Supplier's submission.
- There is no plan to mitigate identified risks on quality or delivery.

- Smiths Detection considers it appropriate (at its discretion) to not authorize the change.

Smiths Detection shall be notified of planned changes prior to implementation using the Supplier Request for Change Form. The implementation date shall be determined by Smiths Detection and the Supplier. The acceptance criteria for a planned change shall be agreed upon by Smiths Detection and the Supplier prior to implementation. New process and product capability studies and approvals may be required as a result of the planned changes. Due to the risks associated with product and process changes in general, the process for accepting a change may require substantial time, to ensure that all risks are understood and mitigated. Where required, Smiths Detection will qualify the product or process change through a new PQP submission. Refer to section 3.5 for additional information. No changes can be implemented without prior written approval by Smiths Detection.

6. Performance Management and Continuous Improvement

Smiths Detection requires its Suppliers to achieve and maintain zero defects and 100% on time delivery. Suppliers are expected to perform regular reviews, at planned intervals, to ensure continued suitability, adequacy, effectiveness, and alignment with meeting these objectives. Smiths Detection continuously monitors the performance of its Suppliers using Key Performance Indicators (KPIs) that are designed to evaluate quality and delivery performance throughout the Product Life Cycle. These KPIs are established to:

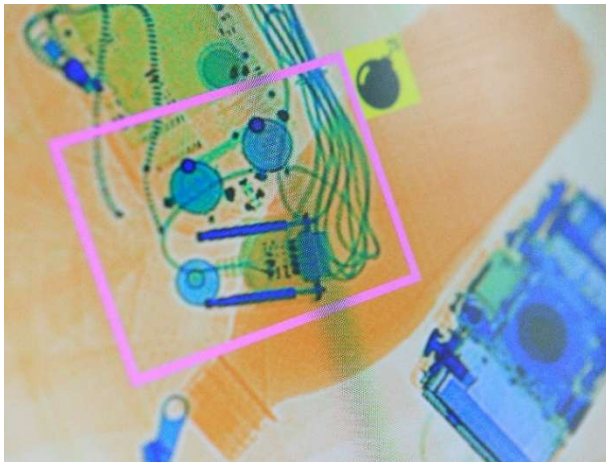
- Enable continuous Supplier performance monitoring and analytics.
- Define necessary strategies and approaches for Supplier performance improvement activities.
- Continuously improve Supplier performance.

Smiths Detection will update Supplier performance data monthly and Suppliers can access their performance data through inquiries sent to Smiths Detection. The company will also hold quarterly and annual reviews with the Suppliers, where Smiths Detection deems this is required. The Supplier's performance is considered for future sourcing decisions and to identify opportunities for continuous improvement projects. It serves also as input for the escalation process, where inadequate performance and a failure to take corrective actions may lead to the initiation of a new business hold or business hold status.

Suppliers are expected to have an internal continuous improvement programme that takes input from both the internal and external quality and delivery performance data. The Supplier shall strive to continually improve its products, processes, and systems through conducting regular reviews of:

- Regulatory and contractual compliance
- Quality policy and objectives
- Internal and external audit results
- Data analysis of quality and delivery performance
- Corrective and preventive actions

Additionally, Smiths Detection may require a Supplier to participate in a Supplier Quality Improvement Programme (SQIP) where its performance is deficient. As soon as a Supplier is identified for participation in an SQIP (i.e., based on performance), a notification will be sent to the Supplier to trigger the activity. The exit criteria will be defined and agreed with the Supplier. The Supplier shall cooperate with the SQIP through the engagement of internal relevant departments, facilitating the SQIP reviews, conducting self-audits where required and addressing the poor performance areas with improvement actions. Upon successful implementation and verification of the agreed corrective actions and once exit criteria are met, the Supplier will be upgraded from the SQIP.



7. Document Control and Record Retention

7.1. Document Control

Suppliers shall maintain an effective Document Control procedure that prevents the deterioration or loss of documents while providing easy access to up-to-date documents. The procedure shall be based on a centralized filing system for hard and electronic documents. In the case of paperless document management, the system shall be effectively managed to ensure that version, identification, storage, and distribution are well controlled. Changes and amendment to documents shall be approved by authorized personnel before implementation. Internal procedures shall be periodically reviewed and approved for suitability and adequacy. Moreover, timely and periodic purging of the centralized system shall be periodically performed to ensure the system is up to date with current information and to control the obsolescence and archiving of documents.

7.2. Record Retention

The Supplier shall establish a robust process to maintain readable and readily accessible records to provide evidence of compliance with legal and regulatory requirements, as well as Smiths Detection requirements set forth later in this section. Records retention policies shall define requirements for paper as well as for electronic records and shall define the length of time that records will be held which shall comply with statutory requirements where applicable.

The Supplier's employees, contractors, and agents who create, receive, use, or manage these records are required to comply with the policies and procedures in accordance with contract and regulatory requirements.

The Supplier is required to retain a copy of the approved PQP documentation for the period of life of production plus 10 years after the last production run.

The Supplier is required to maintain all records relating to quality inspection, product testing data and counterfeit verification data for a minimum of 10 years after the last production run.

The Supplier is required to maintain records of authorized signatures used on work orders, planning documents, inspection plans, test reports or certificates for a minimum of 10 years after the last production run.

The Supplier is required to maintain radiation relevant records for a minimum of 30 years from creation, and asbestos related records for a lifetime.

These requirements may change based on regulatory, contractual or customer requirements. The Supplier shall provide records to Smiths Detection when requested.

The sections of this Manual that require records shall conform to this retention policy.

8. Appendices

8.1. Appendix 1 : Requirements

- www.asq.org/quality-resources/iso-9001 : "WHAT IS ISO 9001:2015 – QUALITY MANAGEMENT SYSTEMS?"
- www.asq.org/iso-14001 : "WHAT IS ISO 14001:2015 – ENVIRONMENTAL MANAGEMENT SYSTEMS?"
- www.zvei.org/technical-cleanliness-in-electrical-engineering-guideline: "Technical Cleanliness in Electrical Engineering, Dirt is simply matter in the wrong place" 2nd extended edition – 2020

8.2. Appendix 2 : Definitions

The following publications are available from the AIAG website at:

- www.aiag.org/FMEA-4: Potential Failure Mode and Effects Analysis Manual, 4th Edition
- www.aiag.org/CQI List: CQI's: Special Process Assessments

The following publications are available from the American Society for Quality at www.asq.org :

- www.asq.org/eight-disciplines-8d: 8D/ "WHAT ARE THE EIGHT DISCIPLINES (8D)?"
- www.asq.org/fishbone: Root Cause Analysis/ "FISHBONE DIAGRAM"
- www.asq.org/five-whys: Root Cause Analysis/ "FIVE WHYS AND FIVE HOWS"
- www.asq.org/flowchart: Process Flow / "WHAT IS A FLOWCHART?"
- www.asq.org/five-s-tutorial: 5S/ "WHAT ARE THE FIVE 5'S (5S) OF LEAN?"

8.3. Appendix 3: Product Qualification Process Requirements

Smiths Detection follows a Product Qualification Process (PQP) methodology which consists of the validation of process and product through verification of documentation including but not limited to Process Flow Chart, Control Plan, FMEA, test results, etc. This is to verify the quality and suitability of supplying parts to Smiths Detection. The PQP shall be followed in an organized, tabulated format for submission to Smiths Detection. The full content of the PQP submission and timing should be discussed and decided with the Smiths Detection Supplier Development Engineer (SDE) and the Supplier's representative.

PQP is to be submitted for all new products based upon their criticality, complexity, and design requirements along with a First Article Inspection (FAI). Also, PQP and FAI may be required for new Supplier, new process, process changes, design changes, any new, modified, or change to tooling, changes in material, or any other change impacting the part and/or process. A PQP checklist will be provided for each PQP, according to Smiths Detection SDF-06 "PQP Requirements Tracker".

To achieve a full PQP release, all elements and FAI must be submitted with a satisfactory result. Any unsatisfactory element or FAI will result in rejection until the unsatisfactory element is resolved. It is possible to achieve a "Provisional" release of the PQP for a minor deviance which will be resolved and then allow for a full release later. Parts on a provisional approval can be shipped to Smiths Detection on a fixed piece quantity or on a time limit until full approval is realized.