External Providers of Products and Services Quality Requirements

Issue.	Date	Description of Revision	Page(s) Revised	Originator
01		First Issue	--	

1. General Requirements.

1.1 Introduction.

This document establishes the quality assurance requirements for external providers of process, product and service pursuant to AMI-CON's purchase orders, these requirements must be flowed down to any sub-tier providers in the supply chain.

The supplier Quality Assurance System shall be based upon national standards, considerations of complexity of product design, criticality of the product's intended use, interchangeability requirements and manufacturing techniques. The Quality Assurance System shall be approved prior to the supply of product or service and shall provide assurance that adequate control of quality is maintained. Approved external providers shall invoke the contents of this document onto their external providers as appropriate to ensure quality of process, product and service.

1.2 Scope.

This document defines the Quality Management System requirements for external providers of products and services to AMI-CON. The requirements shall be complied with in addition to all detailed requirements of the purchase order, any deviation from compliance with this document shall be submitted to AMI-CON's Quality Department.

1.3 Access Clause.

The external provider shall give right of access to AMI-CON, customers and regulatory authorities representatives. Sufficient notice shall be given prior to any activities which may include assessments /audits (including sub-tier providers) prior to or after issue of a purchase order.

AMI-CON representatives may be assigned to an external provider because of new provider selection, provider improvement activities following poor quality, delivery performance or new product introduction. The responsibilities and authorities delegated to these representatives include but not restricted to:

- Co-ordinate responses to unsatisfactory conditions
- Conduct initial and periodic QMS base audits or product-based evaluations
- Review and approve First Article Inspection Reports
- Monitor the inspection of product or service against requirements
- When applicable authorise shipment of product and supporting data following source inspection

The review of products and services by AMI-CON, its customers or regulatory representatives does not absolve the external provider of responsibility to provide conforming product or services nor shall it preclude subsequent rejection.

2. Supplier Approval Process.

2.1 Quality Managements Systems Requirements.

AMI-CON's requirement for QMS approval within its supply chain is as follows:

Where compliance with these standards has not been attained, the level of AMI-CON's surveillance activity will be increased.

In order for a supplier to hold an **A rated quality status** the following supplier requirements must be met:

- **An audited quality management system holding a current quality approval issued by a certification body regulated by a recognised authorisation body** i.e. ISO 9001, AS9100 or AS 9120.
- **An authorised Manufacturer or Distributor**
- **Authorised to repack, decant or convert product/material**
- **Can provide a certificate of conformity**
- **Can provide a Manufacturer's certificates of analysis can be supplied upon request** (where applicable)
- **Is compliant with the current REACh (Registration, Evaluation and Authorisation of Chemicals) Regulations and actively disseminate material changes downstream**.
- **Adequately complete CF004 Supplier Quality Assurance Questionnaire (SQAQ).** Not required if the vendor is an OEM and meets all over criteria
- **Provide Full traceability of the product/material back to source.**

In order for a supplier to hold a **C rated quality status** the following supplier requirements must be met:

- **Operates a functional and effective QMS**. **Preferably holding a current quality approval issued by a certification body regulated by a recognised authorisation body**. ISO 9001
- **Can provide a Manufacturer's certificates of analysis can be supplied upon request** (where applicable
- **Is compliant with the current REACh (Registration, Evaluation and Authorisation of Chemicals) Regulations and actively disseminate material changes downstream**.
- **Adequately complete CF004 Supplier Quality Assurance Questionnaire (SQAQ).** Not required if the vendor is an OEM and meets all over criteria
- **Provide Full traceability of the product/material back to source.**

In order for a supplier to hold a **U rated quality status** the following supplier requirements must be met:

- **The supplier must provide adequate documentation to support the materials supplied that supports conformity and negates the potential supply of counterfeit parts.**
- **Is compliant with the current REACh (Registration, Evaluation and Authorisation of Chemicals)**

2.2 Approval Process.

New suppliers shall be evaluated prior to the placement of a purchase order or contract. Suppliers who successfully complete initial evaluation, consistently meet the criteria of a Preferred Supplier rating (see section 3) and maintain the relevant approval status as above will be re-evaluated periodically for continuity and continuous improvement.

For suppliers who do not maintain either an acceptable quality rating or approval and/or require an official review as per the mechanism laid out in section 3. AMI-CON reserve the right to withdraw a supplier's approval, wholly or in part at any time.

The method of evaluation of suppliers may include either on-site QMS assessment, product-based evaluation or by methods including but not limited to methods documented within this publication.

Note: It is at the sole discretion of AMI-CON to evoke an on-site evaluation of external providers whether AS9100, ISO9001 or AS9120 approved or not.

2.3 Assessment Results.

When a supplier assessment is required, the supplier shall be notified where the date and content of the assessment will be agreed. The results will be documented in an assessment report and presented to the supplier for action as required. Failure to provide acceptable corrective and preventative actions to findings within agreed timescales may result in failure to approve or approval suspension. The classification of corrective and preventative actions are as follows.

Classification	Quality System	Product Implementation	Target
MAJOR	A non-conformance which may result in the partial or total failure of an element of the Quality System	Stops the production or development process and questions the Conformance of the product(s) or service(s)	Within 5 working days or within a period agreed by AMI-CON
MINOR	A failure that may cause non-conformances that are not considered MAJOR		Within 28 days or within a period, agreed by AMI-CON
Observation	An opportunity for improvement identified to improve the effective operation of the Quality System or business		Although advised, no formal response required

Table 1

3. Vendor Rating Policy.

The AMI-CON vendor rating system is designed to measure, evaluate and improve external provider performance, enabling AMI-CON to make informed future sourcing decisions.

The rating system is designed to meet the specific objectives and priorities of the business with external providers being measured against a standardised scale. The criteria of this scale are detailed in table 2 below and is based on 'Right First Time' (RFT) 'On Time in Full' (OTIF) percentage of products or services delivered to AMI-CON.

External providers are required to achieve a rating of Preferred Supplier for all products delivered to AMI-CON. External providers who fall this standard will be contacted by AMI-CON to ensure a suitable action plan is generated to achieve a Preferred Supplier status for future deliveries. The action plan will be monitored by AMI-CON, during this period the external provider shall be expected to maintain and report on controls or actions imposed by AMI-CON.

External providers will receive notification of rejects (which directly affect vendor rating) by receipt of a Non-Conformance Report (NCR). External providers are required to respond to the NCR within the timescale specified in table 1 of this document. Where external providers have objective evidence to show they have been incorrectly rated objective evidence must be provided in support of the NCR response and as a result if agreed liability will be amended.

Where parts are found to be non-conforming or counterfiet at AMI-CON the external provider must make arrangements for the collection of defective parts or provision of shipping details.

VENDOR RATING	**CRITERIA**
Preferred	≥ 95% (RFT) (OTIF)
Improvement Required	≥85% to <95% (RFT) (OTIF)
Official Review Required	< 85% (RFT) (OTIF)
All data is based on a month rolling average.	

Table 2

4. Supplemental Requirements.

4.1 Requirements from External Providers.

AMI-CON shall ensure that requirements shall be communicated to external providers regarding but not limited to:

- Drawings, specifications, process requirements (including special processes) and any other technical data to ensure conformity of process, product or service.
- Approval of processes, products, services, equipment and subsequent release of processes, products and services.
- Interaction of the external provider with AMI-CON.
- The extent of control on the external provider AMI-CON shall apply.
- Verification and validation activities AMI-CON or its customers shall perform at the external providers premises.
- Design and development controls.

- Define any critical items that include key characteristics.
- Test and inspection criteria including production process verification activities.
- Statistical techniques for acceptance of product by AMI-CON

The external providers shall ensure:

- It has established a Quality Management System.
- It uses customer designated or approved sub-tier.
- The external provider shall make AMI-CON aware of any non-conformance of process, product or service provided.
- External providers have a procedure to prevent the use or delivery of counterfeit products to AMI-CON.
- Shall notify AMI-CON of any change to process, product or service including but not limited to change in manufacture location.
- External providers shall flow down all requirements for process, product and service to any sub-tiers.
- Provide as required test specimens, production methods, storage conditions and inspection /verification activities.
- Retention of documented information including retention period in accordance with EN9130 or as defined on the purchase order.
- Ensuring persons within the external provider and any sub-tiers are aware of their contribution to compliance, product safety and ethical behaviour.

4.2 Inspection.

The external provider shall not use sampling inspection methods in lieu of 100% inspection without the prior written approval of the AMI-CON Quality Manager. Information required to support sampling inspection proposals shall include but not limited to:

- Sampling inspection scheme proposal.
- Process capability /gage R&R study results.

Personnel performing inspection or critical manufacturing operations shall be subject to a regular eye examination.

4.3 First Article Inspection.

The purpose of the First Article Inspection (FAI) process is to provide objective evidence that all design and specification requirements are correctly understood, accounted for, verified and recorded via a repeatable and robust manufacturing process. AMI-CON requires FAIR compliance in-line with AS9102 standard.

The following points supplement AS9102 standard:

- Any non-conformance reports shall be appended to the FAIR.
- Where kits /assemblies are produced AS9102 form 1 shall be collated for the deliverable parts numbers with forms 1, 2 and 3 being generated for respective detail parts.
- Material test certificates /reports and manufacturing records (job cards) shall be collected and appended to the FAIR.
- Associated C of C’s shall be annotated to state that the parts are subject to a FAIR.

4.4 Certificate of Release.

A Certificate of Conformity (C of C) must be provided with all deliveries and shall identify with the following as a minimum where applicable:

- All C of C's shall be signed by persons with scope of authority to do so.
- Specification/release must be stated (where applicable).
- Any special process and relevant specification (where applicable).
- FAIR's and /or NCR's must be referenced (as applicable).
- QMS accreditation number referenced.
- Product subject to shelf life control shall have the date of manufacture, expiry date and remaining out-life of product clearly stated on the C of C.

Note: A combined C of C and delivery note is acceptable.

4.5 Packing

Unless otherwise specified by AMI-CON in the purchase order the following shall apply.

When provisioning packing materials the following shall be considered:

Materials used are specifically produced and procured for sealing, bagging, cushioning and protecting goods whilst in transit.

Selection of materials and cartons used for each consignment must afford adequate protection when taking into consideration fragility, size, weight and method of transportation and shall be suitable for ensuring goods arrive at the customers premises undamaged.

Cartons for shipping transportation must clean, intact and fit for purpose.

Sealing bags must be tape or heat sealing, staples are not to be used.

Where appropriate all pallet loads are to be strapped and / or sealed with either heat shrink polythene or stretch film.

Any specific labelling requirements shall be specified in the purchase order

It is expected that all parts sent to AMI-CON will be transported and packaged with the necessary precautions to prevent damage and contamination of FOD. Any parts received in an unsatisfactory state will be rejected back to the Supplier.

NOTE: THE USE OF SHREDDED PAPER IS STRICTLY PROHIBITED

4.6 Identification and Traceability.

The external provider shall ensure that the product supplied is suitably identified and all associated manufacturing records are annotated for each stage of manufacture, all products shall be released with formal identification.

Products shall be traceable back through the manufacturing process, this shall include lower tier sub-contractors and shall include traceability back to raw material.

4.7 Record Retention.

The external provider shall retain records in either hard copy or electronic data, records shall cover the entire manufacturing process from purchase of raw materials to certification of final product.

AMI-CON requires adequate quality system records to demonstrate the conformity of the product to be retained for a minimum of 10.

NOTE: THE USE OF CORRECTION FLUID IS STRICTLY PROHIBITED ON ALL QUALITY RECORDS.

4.7 Continuous Improvement.

With the challenges posed by industry there is a need to improve AMI-CON's supply chain. To meet these requirements, it is expected external providers will support this by independently engaging in a recognised continuous improvement programme.

4.8 Materials Hazardous to Health & Environment.

The external provider must ensure compliance with the respective national and /or international regulations and legislation i.e. UK REACH & EU REACH. The external provider has an obligation to ensure compliance of its sub-tier supply chain.

****Where hazardous materials are supplied to AMI-CON, the external provider has the obligation to make available prior to despatch the associated Material Safety Data Sheets ****.**

4.9 Changes to Process, Product, Supply Chain or facility.

Suppliers are required to obtain documentation of AMI-CON approval prior to implementing any applicable change as listed below. This requirement applies to direct material suppliers, including distributors.
Applicable 'changes' include but are not limited to:

- Approved Production Process
- Materials (Material sources are restricted by virtue of design requirements specified in the Drawing, Bill of Materials and Approved Supplier Listing).
- Change of Sub-Tier Suppliers for raw materials, purchased components or services
- Change to test/inspection sequencing or methods
- For bulk material suppliers: Alternative source of raw material from new or existing Suppliers
- For distributors: Alternative sources of component parts other than those previously qualified
- Changes in third party certification status.

4.10 Control of Non-conforming Material.

The Supplier shall have controls in place that assure for control, identification and segregation of non-conforming material.

For all non-conformances identified by AMI-CON either through an internally raised Non-Conformance Report (NCR) or Supplier Corrective Action Request (SCAR) notification, the

Supplier shall submit a formal corrective action response with containment actions and a corrective action plan. The Supplier shall also provide supporting evidence of corrective actions taken to prevent recurrence of the issue.

If known non-conforming product has escaped the Supplier's facility (and has been shipped to AMI-CON), the Supplier will notify their respective AMI-CON purchasing contact and Quality representative immediately.

For product that has been found or suspected non-conforming prior to shipment to AMI-CON, all requests for approval for concession to use as is, or production permit to allow deviation from process, must be submitted to the AMI-CON procurement specialist, for approval. All material must be held at the Supplier's address pending receipt of documented AMI-CON approval on formal NCR and amended PO, prior to further processing and/or shipment of nonconforming material.

Note: The NCR shall be referenced on the release documentation.
Failure to respond to a corrective action request may result in penalties up to and including suspension and/or removal from the AMI-CON Approved Supplier List.
Note: AMI-CON reserves the right to re-claim expenses incurred where it is clearly deemed and agreed that the supplier has full responsibility for the non-conformance.

4.11 Anti Counterfeit Process.

The Supplier shall implement an appropriate strategy to ensure that counterfeit articles are not delivered to AMI-CON. The Supplier's strategy shall include the direct procurement of articles from OEMs or authorized distributors, conducting approved testing or inspection to ensure their authenticity.

Counterfeit articles delivered or furnished to AMI-CON are deemed nonconforming. If the Supplier becomes aware or suspects that it has furnished counterfeit articles to AMI-CON, the Supplier shall promptly notify AMI-CON and replace, at Supplier's expense, such counterfeit articles with OEM or Buyer-approved conforming articles. The Supplier shall be liable for costs related to the replacement of counterfeit articles and any testing or validation necessitated by the installation of authentic articles after counterfeit articles have been replaced.
The Supplier bears responsibility for procuring authentic articles or items from its subcontractors and shall ensure that such subcontractors comply with these requirements.
Any potential suspect unapproved parts / counterfeit material that have been found by the Goods Inward Inspection will be immediately quarantined and the Quality Department advised. If the suspect unapproved parts / counterfeit material is confirmed by a subsequent investigation, the Quality Department will inform the local authority office of its findings in accordance with AS6174.

4.12 Obsolescence Management.

All Suppliers shall have an Obsolescence process. This process should be proactive in ensuring identification of potential obsolescence in parts, components, materials supplied to them.

The Supplier shall also have a process that ensures AMI-CON are proactively advised of any potential obsolescence issues in respect to parts, components, materials that AMI-CON may procure from them.