Control of Externally Provided Processes, Products and Services

1.0 Purpose
To ensure that Fleet Canada states applicable requirements for purchased products on purchase orders and applicable documents. Requirements may be from primes, regulatory and/or internally generated.

2.0 Scope
This procedure is applicable to Fleet Canada and all applicable suppliers. Suppliers listed on the Fleet Canada Approved Vendor List (AVL) shall be controlled to the type and extent dependent upon the effect of purchased product on subsequent product realization or the final product.

3.0 References
- AS9100D Quality Management Systems – Requirements for Aviation, Space, and Defense Organizations
- QAM Quality Assurance Manual
- QAP 5.2 Quality Policy
- QAP 7.2 Competence
- QAP 7.4 Communication
- QAP 7.5 Documented Information
- QAP 8.4 Control of Externally Provided Processes, Products and Services
- QAP 8.4.2d Verification Activities - Receiving Inspection (was QAP10.1)
- QAP 8.5.1.3 Production Process Verification - First Article Inspection
- QAP 8.5.2 Identification and Traceability
- QAP 8.5.3 Property belonging to Customers or External Providers
- QAP 8.5.4 Preservation
- QAP 8.7 Control of Nonconforming Outputs
- QAP 9.3 Management Review
- QAP 10.0 Improvement
- QAP 11.2 Digital Product Definition
- WI-019 Risk Management Process
- QAP 8.4 Attachment 1 - Supplier Quality Requirements

4.0 Responsibility
The Quality Assurance Manager, or designate, is responsible for defining the process, responsibilities and authority for the approval status decision, changes to the approval status, and conditions for a controlled use of suppliers – reference AVL.

4.1 The Purchasing Manager is the formal Fleet Canada contact with subcontractors, and is responsible for:
(a) the initiation, content, addition and revisions to Procurement Department Work Instructions;
(b) training Purchasing personnel in the requirements and methods used to purchase production and non-production items (as defined by Fleet Canada Inc. or customer requirements);
(c) liaise with customers, control desktop questionnaire, and other unspecified departmental tasks.

4.2 Fleet shall be responsible for the conformity of all externally provided processes, products, and services, including from sources defined by the customer.
5.0 Definitions
CoA – Certificate of Analysis
CoC – Certificate of Conformance
DCAN - Defect and Corrective Action Notice form FQA0005
DPD - Digital Product Definition
Supplier Quality Audit Report (form FQA0126
Supplier Audit – form FQA0010
DMR-VRR (Vendor Rejection Reports)

6.0 Procedure
Fleet considers the potential impact of the externally provided processes, products, and services on Fleet's ability to consistently meet customer and applicable statutory and regulatory requirements.

6.1 Control of externally provided processes, products and services
The Fleet Purchasing department shall issue a document package with POs and shall ensure that orders/agreements, including blanket orders, contain the following information, where required:

(a) contract number (e.g. PO#/RFQ#, etc.);
(b) vendor's name and address;
(c) complete and clear description of the material and service;
(d) First Article requirements;
(e) the type, class, style, grade or other precise identification;
(f) applicable issues of specifications, drawings, process requirements including revision status, where applicable;
(g) inspection/verification instructions or other relevant technical data;
(h) requirements for approval or qualification of product, procedures, process equipment and personnel;
(i) title and issue of quality system standard to be applied;
(j) shipping/packaging instructions;
(k) Requirements for design, test, inspection, verification (including production process verification) and related instructions for acceptance by Fleet, and critical items including key characteristics, where applicable;
(m) Customer PO Clauses, Key Characteristics, DPD requirements and other unspecified documentation shall be flowed down to the subcontractor, where required;
(n) Supplier quality requirements (reference section 6.2), right of access, QMS, other.
(o) Terms and Conditions

6.1.1 Approval of Purchase Orders
Purchase orders and amendments shall be reviewed and approved by Purchasing. Purchasing shall ensure purchase orders comply with the requirements listed below:

(a) subcontractor is on Fleet's vendor approval list, customer approved vendors list and currently approved or conditionally approved, if applicable;
(b) the applicable issue, revision, and amendment of the controlling Engineering Order or specification is specified, as applicable;
(c) the subcontractor's responsibility for carrying out processes called up on the drawing is defined and when required to cross reference the part number being released to the batch number of the process;
(d) the quality control/inspection requirements, as applicable;
(e) qualification requirements for process, equipment, product or personnel, as applicable;
(f) special packaging requirements, where required;
(g) if certification is required, then release notes, affidavits, test reports, etc. are specified;
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(h) the required test coupons or material for testing of processes/special processes are specified;
(i) FAI requirements;
(j) requirements for cure date or manufacture date to be stamped on each item or container and for indications shelf life, as applicable;
(k) the rights of access by Fleet Canada, Customers, or authorities to the premises of subcontractors at any level of the supply chain for verification.

6.1.2 Any request for source inspection, customer or government inspection at subcontractor's facilities to be arranged through QA/Contracts who will arrange for amendments to purchase orders to include reasonable requests.

Fleet Canada reserves the right to perform source inspection at the subcontractor's facility. When specified on the purchase order, the subcontractor shall notify Fleet in a timely manner (target: 48 hours) prior to shipment. Fleet also reserves the rights of access to subcontractor's facilities for its customer and authorities for verification of product and processes to ensure conformity to specified requirements. Subcontractor notification of product / process readiness (target: 48 hours) shall be made to Fleet Purchasing who will make arrangements with customers for verification. The subcontractor shall make available the resources, facilities and equipment to facilitate any such inspections required.

6.1.3 Purchase orders and amendments are available for review by Quality Assurance, as required.

6.1.4 Delegation
If Fleet delegates verification activities to the external provider, the scope and requirements for delegation shall be defined and a register of delegations shall be maintained. Fleet shall periodically monitor the external provider's delegated verification activities. Reports of external verification shall be provided to Fleet as required.

6.2 Supplier Quality Requirements
Fleet shall ensure that externally provided processes, products, and services do not adversely affect Fleet's ability to consistently deliver conforming products and services to its customers, and shall:

(a) ensure that externally provided processes remain within the control of its quality management system e.g. through Supplier Quality Requirements;
(b) conforms to customer requirements;
(b) define both the controls that it intends to apply to an external provider and those it intends to apply to the resulting output;

Fleet requires external providers apply appropriate controls to their direct and sub-tier external providers, to ensure that requirements are met.

6.2.1 Fleet Customer Information/Data Flowdown to Suppliers
Fleet Purchasing shall ensure the adequacy and accuracy of requirements prior to their communication to the external provider and shall communicate to external providers Fleet's Supplier Quality Requirements – reference QAP 8.4 Attachment 1.

6.2.2 DPD Flowdown
Fleet will identify DPD and MBD capable suppliers on Fleet's approved supplier list when datasets are provided for manufacturing, inspection, or tool design or tool build and comply with requirements of D6-51991.
D6-51991 requirements will be flowed down in purchase documents when digital data is provided to suppliers. Flow down to suppliers and from suppliers to sub-tier suppliers shall be in compliance to export/import requirements (such as ITAR, MLA, MA, TAA, and EAR). Controlled Goods information (e.g. digital data) shall be logged into a Transfer/Disposal Record Log for tracking purposes.

All DPD data provided to and received from Fleet suppliers shall be encrypted prior to transmission per Fleet Procedure QAP 11.2. Unencrypted datasets will not be used and shall be contained until disposition by the provider.

Note: When suppliers provide MBD models to sub-tier suppliers, the supplier must ensure that the sub-tier supplier can view the annotation, flow MBD information to manufacturing and inspection, perform a complete AS9102 FAI, and have training in place.

6.2.3 Verification Activities – Receiving Inspection
Fleet shall ensure that purchased product conforms to specified purchase requirements. Product verification upon receipt is performed in accordance with QAP 8.4.2d. Where Fleet delegates verification activities to a supplier, the requirements shall be defined and a register of delegations shall be maintained.

Customer verification activities performed at any level of the supply chain shall not be used by FCI or it’s suppliers as evidence of effective control of quality and shall not absolve FCI of its responsibility to provide acceptable product and comply with all requirements. Fleet shall be responsible for the conformity of all externally provided processes, products, and services, including from sources defined by the customer.

Initial acceptance at source or incoming does not relieve the subcontractor the responsibility to supply acceptable product and comply with all requirements nor does it preclude subsequent rejection by Fleet or its Customer.

6.2.4 CofC review validation
When external provider test reports are utilized to verify externally provided products, Fleet evaluates the data in the test reports to confirm that the product meets requirements. When a customer identifies raw material as a significant operational risk (e.g., critical items), Fleet shall implement a process to validate the accuracy of test reports.

6.2.5 Nonconforming Outputs
Fleet defines the necessary actions to take when dealing with external providers that do not meet requirements in QAP 8.7 (and this document).

6.3 Risk
Fleet shall identify and manage the risks associated with the external provision of processes, products, and services, as well as the selection and use of external providers. For example, factors that can be used during supplier selection and evaluation are, but are not limited to:

(a) Supplier quality data from objective and reliable external sources;
(b) Accredited quality management system information;
(c) Process certification information;
(d) Other, as evaluated by Fleet.
Fleet Quality maintains a simple supplier risk evaluation using the following formula:

\[(\text{Location risk}) \times (\text{# weeks leadtime}) = \text{Risk# (High/Medium/Low)}\]

Where (Location risk) is defined to be (1) if Canada, (2/3) Other country e.g. USA, etc.

Risk is Low if the calculated # is <10
Risk is Medium if the calculated # is >=10 but less than 20
Risk is High if the calculated # is >=20

The risk of selection and use of suppliers shall be determined by the Quality Assurance Manager, or designate, based on supplied or obtained supplier information (such as lead-time and supplier location) and documented on form FQA0126 (for example, “High” risk suppliers shall be indicated to be “High”, etc.).

6.3.1 Product released at Risk
When externally provided product is released for production use pending completion of all required verification activities, it shall be identified and recorded to allow recall and replacement if it is subsequently found that the product does not meet requirements.

6.3.2 Counterfeit Product – reference QAP 8.1.4
Traceable material shall be acquired only through customer approved suppliers as defined by Purchase Order and/or customer contract. Fleet has implemented the following strategy to ensure furnished goods are not counterfeit by mitigating counterfeit product risk via the following methods:

- Flow down of PO requirements QAP 8.4 section 6.2
- Procurement from authorized suppliers QAP 8.4 section 6.4
- Conducting testing/verification/inspection QAP 8.4 sections 6.2.3, 6.2.4
- Certification QAP 8.6 section 7.1.3
- Supplier Quality Requirements QAP 8.4 section 6.2

6.3.3 Material Testing Verification
Periodic validation of raw material shall be performed where required by customer or statutory/regulatory requirements with a frequency of five (5) years.

Periodic validation of raw materials received with a certificate shall be performed to ensure conformance of the material to the procurement requirement. QA have the prerogative to modify the testing cycle according to quantity of purchase order released and the number of rejections, customer/regulatory requirements as necessary.

When Material testing verification is required, Quality will raise a Material Testing Request (form FQA0009) to identify:

(a) sales release number
(b) supplier name
(c) purchase order number
(d) material description
(e) material specification
(f) material type
(g) test piece quantity and size
(h) tests required
(i) signature for the request
(j) department request raised in
The Material Testing Request shall be forwarded to the Procurement Department who shall review the request and provide for the piece of material for testing. Both request and material shall then be forwarded to Quality who will ensure validity of sample, identify accordingly, and forward the sample with a copy of applicable documents to the Laboratory for testing, or arrange for subcontract testing by an independent facility.

Review of Results
Upon receipt of results, Quality shall compare the actual results to the specifications and original certificates. If the material complies with the requirements, the test report shall be signed or stamped by the Laboratory Technician (or delegate) and the test report retained/filed.

When unsatisfactory test results are received, the material shall be rejected immediately per QAP 8.7. All materials received from that vendor are to be verified until a satisfactory level of confidence is achieved. Purchasing shall then notify vendors, as appropriate, the details of the test report. QA shall maintain a file of Material Testing Requests, laboratory tests and results in accordance with QAP 7.5, or per contractual requirements.

Types of Tests: Examples of typical required tests (not meant to be an exhaustive list) to be performed to meet customer requirements:

- **Metals:**
  - (a) hardness and conductivity
  - (b) tensile tests - ultimate yield and elongation
  - (c) chemical tests - verify random results to specification requirements

- **Other e.g. Tank contents, Adhesives, etc:**
  - (a) chemical, honeycomb and other materials as called out in the appropriate specifications

6.4 Subcontractors Type/Control
Fleet shall determine and apply criteria for the evaluation, selection, monitoring of performance, and reevaluation of external providers, based on their ability to provide processes or products and services in accordance with requirements.

6.4.1 Selection of Subcontractors
The Procurement Dept. is responsible for the initiation of all new subcontractor qualification, selects suppliers based on their ability to supply product, forwards audit requests and acts as the formal Fleet Canada contact with subcontractors. Procurement shall forward the Supplier Audit Basic Data Questionnaire (form FQA0010) to the subcontractor and return the completed form to Quality Assurance.

Procurement shall purchase production materials, processing or items directly related to a production products quality only from subcontractors listed on Fleet's AVL/Customer AVL and must take into consideration special processes requiring Prime approval to which the subcontractor must be approved. Where required, Fleet and it’s suppliers shall use customer approved special process sources.

Special Processes
Fleet shall ensure, when required, that customer-designated or approved external providers, including process sources (e.g., special processes), are used.
6.4.2 Supplier Recognition/Evaluation

During external provider evaluation and selection, Fleet can use quality data from objective and reliable external sources (e.g., information from accredited quality management system or process certification bodies, external provider approvals from government authorities, customer mandated, or other). Use of such data would be only one element of Fleet’s external provider control process and Fleet remains responsible for verifying that externally provided processes, products, and services meet specified requirements. Supplier evaluation may include the review of supplier quality data from objective and reliable external sources (e.g., information from accredited quality management system or process certification bodies, or organization approval from government authorities, etc.), the audits mentioned in section 6.4.6, and where necessary review of supplier quality management system documentation. Analysis data generated as a result of supplier monitoring and measurement activities, and from other relevant sources are included in Management Review meetings, as required.

6.4.3 Maintain a Register (AVL)

Fleet shall maintain a register of approved vendors providing any consumable materials or services used in the manufacturing of production materials that includes the scope of the approval – this register is called the Fleet Approved Vendor List (AVL). The register of approved suppliers (e.g. AVL) shall include the scope of the approval. Examples of suppliers (not meant to be an exhaustive list) would be customer mandated and/or Special Processors, Laboratory suppliers/services, Calibration sources, DPD related services, etc.

6.4.4 Approval Status Decision

The Quality Assurance Manager, or designate, is responsible for the approval status decision, changes to the approval status, and conditions for a controlled use of suppliers (i.e. special processes, customer mandated, etc.). Subcontractor audits may be requested at any time QA deems necessary based on quality of product, quality history, recurrence of rejection, or failure of corrective action. In all cases continued approval or conditional approval is subject to subcontractor’s demonstration of capability and performance to Fleet’s requirements and subject to verification upon receipt. The general default approval timeframe is set to every 5 years – note that this frequency of periodic review may be altered by the Quality Assurance Manager dependent upon each individual situation.

Fleet shall define the process, responsibilities, and authority for the approval status decision, changes of the approval status, and conditions for a controlled use of external providers depending on their approval status. Fleet Vendor Status is categorized via the following classes:

A = Approved  C = Conditional  D = Disapproved

Approved

Where a review of supplier quality data determines that the supplier is able to supply product in accordance with Fleet’s requirements, that supplier shall be granted “Approved” status. This may be based upon information from accredited quality management system or process certification bodies, or organization approval from government authorities, etc.
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Conditional
Where a review of supplier quality data indicates that a supplier is able to supply product in accordance with Fleet’s requirements, but specific issues have been raised, that supplier will be assigned “Conditional” status. A Purchase Order may be issued but, depending upon the circumstance, additional inspection or restrictions may be imposed on the supplier. Exceptions to Fleet’s Vendor approval must be directed contractually, then QA will list the subcontractors as conditionally approved without audit per customer requirements.

Approved and Conditional vendors may be issued purchase orders.

Disapproved
If a review of supplier product/services shows the supplier to be a concern (i.e. product does not meet requirements, or the supplier fails to address a DCAN, or other unspecified reason), the supplier may be given Disapproved status. See additional guidance concerning rejected material in QAP 8.4.2d.

Procurement inactivity for a ten year period shall cause the subcontractor listing to be shown as Disapproved due to inactivity. This type of listing may become active by Procurement’s issuance of a successful Request for Audit (reference section 6.4.6). Any purchase orders outstanding with a disapproved subcontractor may be subject to specific orders from the Quality Assurance Manager and may require source verification of all work performed at the subcontractor’s facility. Procurement shall perform quarterly reviews of Fleet’s AVL. When a supplier is found to be within 3 months of expiry, Fleet Procurement will send a FQA00010 form in order to renew the vendor’s approval status. In the event the vendor does not return the completed paperwork back by the expiry date, Procurement will request the supplier be moved to inactive status and cannot be used, unless specifically approved by Fleet Quality Manager.

6.4.5 Subcontractor Categories
The Approved Vendors List shall categorize subcontractors into the following classes:

C = Prime (Customer Supply)
D = Distributor
M = Manufacturer
P = Process (e.g. subcontractor, work in process)
S = Service
X = Minor Purchases (less than $3,000 per year)

Class C is customer supplied materials for incorporation into their final product. This classification is not subject to audit and is covered in QAP 8.5.3 “Property Belonging to Customers or External Providers”.
Class D is for distributors.
Class M is for manufacturers who deliver completed product to requirements.
Class P is for processes i.e. subcontractors, etc.
Class S is for services.
Class X may be applied to any of the above classes - this category recognizes the impracticality of audits on vendors with a procurement of less than $3,000 per annum.
6.4.6 Supplier Audit

Subcontractors to Fleet Canada are subject to audit/survey and approval prior to placement of purchase orders for materials or services which affect quality of deliverable product. Quality Assurance is responsible for establishing Quality Audit Survey requirements, maintenance of subcontractor audit schedule, leading the Quality Audit Survey and assisting as necessary or requesting assistance and support from other technical organizations in order to assess the subcontractors’ capabilities and compliance to the requirements, issue approval, conditional approval, request corrective action, or disapprove subcontractors.

Supplier Audits are categorized in the following classes:

D = Desk
I = Initial/Renewal
M = Maintenance
S = Site

Desk audits are created, sent out and managed by Procurement, but are validated by QA. This type of audit consists of submitted customer data and subsequent review of updated form FQA0010 Audit Basic Data Questionnaire response and quality history of delivered product or services, when required.

Initial/Renewal audits are performed on subcontractors to verify the quality system and assess the subcontractor’s ability to meet Fleet’s requirements, when required.

Maintenance audits are performed on subcontractors listed in Fleet’s vendor approvals and are assessed for continued compliance, when required.

Site audit, or Physical audit, is performed by the FCI representative who acts as team leader and has the responsibility for review and evaluation of the subcontractors’ facilities, procedures, and system. The FCI representative is responsible for completing and distributing the quality audit findings, issuing corrective action reports (DCANs form FQA0005), and debrief with QA and Procurement as required and to ensure all records are updated.

Guidelines for Auditors are covered in section 6.4.7. Current third party certification may preclude the need for a site audit, at the discretion of the Quality Assurance Manager or delegate.

6.4.7 Audit Guidelines

Fleet Canada recognizes third party independent registration of Quality Systems to ISO standards and may waive audits upon receipt of copy of current registration or may choose to audit specific to purchase order requirements.

Fleet Canada (for product such as hardware, paint, chemicals, adhesives, or other liquids) must utilize those vendors whose products are listed as “Qualified” for use as stated in the National Standards Association Publication or customer requirements, when directed by applicable specification. Supplementary Quality Audits are neither necessary nor effective in challenging the ‘qualified’ source of supply. Therefore, the desk audit shall be accepted subject to verification of product. Audits will be performed when proven necessary and as directed by the Quality Assurance Manager.

Auditors must be qualified by having performed previous audits with a qualified auditor, formal training or experience, and approved to perform audits by the Manager, Quality Assurance.
Preparation for Audit (suggested)

- review vendor file including latest audit report
- review sub-contractor’s QA Manual
- review outstanding purchase orders and volume of business in previous year
- review quality history, review VRR’s for last year and responses to corrective actions, take copies for follow-up implementation of corrective actions
- develop, enhance audit checklist or review FQA0223 checklist for applicable sections
- call, confirm date and time of audit
- perform audit to scheduled time, collect any necessary supportive objective evidence
- debrief audit findings before leaving
- upon return, complete Audit Report form FQA0126, complete corrective action requests (DCAN form FQA0005) if required
- debrief with QA for audit approval and rating
- issue letter to auditee, copy Procurement, and update vendor approval list

Supplier Ratings
Fleet periodically reviews external provider performance as applicable (e.g. process, product, service conformity, and on-time delivery performance as required - reference QAP 9.3). Supplier ratings are reviewed at least annually (i.e. Management Review, other):

- outstanding audit corrective actions may necessitate conditional approval regardless of rating
- severity of non-conformances or observations necessitate reduction in rating
- based on 100% accepted product and paperwork (i.e. no DMR-VRRs)

Approval 86% - 100%
Conditional 71% - 85%
Disapproval below 70%

NOTE: DMR-VRR (Vendor Rejection Reports) per QAP 8.7 are forwarded to Subcontractors via Purchasing for corrective action. Failure of response in a timely manner (target: four weeks), or ineffective or unacceptable corrective action necessitates a Defect and Corrective Action Notice (DCAN) to be forwarded to Subcontractor and shall be rated as above.

Fleet Canada bases the quality approval of distributors and wholesalers on the quality history of the vendor and accepts third party certification. Manager of Quality Assurance has the authority to approve, disapprove, or schedule audits based on quality history and performance of subcontractors.

As an example, a new vendor desk audit may be given a conditional approval and the quality of the material will be monitored. Should the new vendor’s quality history prove to be acceptable, then the rating may be changed to Approved. Again, QA reserves the right to audit when proven necessary.
7.0 Record Retention
Fleet shall retain appropriate documented information of these activities as evidence of the results. All Quality and related records are controlled and maintained in accordance with QAP 7.5.

7.1 Supplier Information/Records
QA shall retain records of acceptable subcontractors as stipulated in contractual requirements. Each vendor file shall contain at least the most recent Supplier Quality Audit Report (form FQA0126) and/or appropriate vendor information. Copies of corrective action responses shall be kept in vendor files for follow-up, where appropriate.

QA is responsible for updating Vendor Approval listings on computer database and issuing hard copies (as required) when updates are made. Vendor approvals shall be made available to all buyers, QA, customers and regulatory authorities, as required.

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<tr>
<td>S. Moledina,</td>
<td>K. Joyce,</td>
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<td>Director, Logistics</td>
<td>Quality Assurance Manager</td>
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