

# IN TOLERANCE

## CONTRACT MANUFACTURING

### External provider Quality Requirements

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**Purpose:** Defines and explains quality requirements for external provider and external provider's sub-tiers on products and/ or services purchased by In Tolerance Contract Manufacturing.

**Scope:** This document is invoked by direct reference on the purchase order.

- No deviation from these documented requirements is allowed unless approved by In Tolerance Chief Operating Officer or Quality Manager.
- External provider and processors shall flow down all applicable requirements to all sub-tier external providers and/ or processors.
- Requirements/ instructions documented on the purchase order take precedence over this document in the event of conflict.

#### **Process:**

#### **Acceptance Authority**

The external provider will assure that:

- Processes/ products are completed prior to signing the process documentation
- Processes/ services are performed by those that are qualified/ trained
- Stamps that are used to approve product/ services are appropriately controlled to prevent unintended/ unapproved usage.
- Personnel is trained on the above criteria.

#### **Acceptance Test Reports**

Acceptance test reports shall be maintained per record requirements and provided to In Tolerance Contract Manufacturing when required or requested. Such reports shall include: Chemical and/ or physical test reports, process certifications, raw material analysis, and hazardous material. Test specimens for design approval, inspection/ verification, investigation, and/ or auditing may be requested.

### **Special Process**

When required by the purchase order, NADCAP certification is required for those special processes. See PRI- Network.org/ NADCAP for a complete list for NADCAP governed processes. A Certificate of Conformance with all of the information stated below is required along with a statement complying to with the NADCAP process.

### **Use of External Providers**

Any use of another external provider other than that the work is contracted to, must be customer-designated or an approved external provider in order to perform the process, including those deemed “special processes”.

Customer requirements, as well as any requirements listed in this document must also be flowed down to the external provider.

### **Certificate of Conformance ( C of C )**

A written certification that the parts/ components/ materials/ service supplied to In Tolerance are certified to and have been manufactured/ performed in accordance with applicable standards and/ or specifications. As a minimum, the certificate shall include the following:

- The In Tolerance Contract Manufacturing Purchase order.
- Part Number, if applicable
- Revision Level, if applicable
- Quantity
- Serial Number, when applicable.
- Shelf Life, when applicable.
- Lot Number, when applicable.
- Process performed and to what specification they are compliant to.
  - When specifications are called out on the purchase order, product shall be processed to the latest revisions and documented on the certificate unless specified otherwise. (Obsoleted and/ or superseded specifications must be referenced on the certificate)
- A statement that certifies compliance to the drawing/ specification.
- Signature, date and title of the seller’s responsible representative.

## **Compliance**

- Material external providers must comply with DFARS 252.225-7014, preference for domestic specialty metals alternate 1.
- All external providers must comply with DFARS 252.2004-7012 for cybersecurity controls.
- All external providers must comply with all applicable U.S. export control laws and regulations including the requirements of the International Traffic In Arms Regulation (ITAR). External provider will not transfer any export controlled item, data, or services to include transfer to foreign persons employed by or associated with, or under contract to external provider or external provider's subcontractors, without the authority of an export license, agreement, or applicable exemption or exception.
- All external providers shall have a quality management system in place.
- All calibrations must be traceable to N.I.S.T standards.
- External provider shall meet any applicable statutory and regulatory requirement.

## **Shelf Life**

Materials, or articles having shelf life characteristics shall be identified with manufacturing date, and/ or cure date, shelf life, expiration date, storage condition requirements and any other data pertinent to the supplied materials or articles.

- In Tolerance Contract Manufacturing reserves the right to reject and/ or return any material with less than 80% of shelf life remaining.

## **Competence**

External provider employees will have the required competence and training to consistently provide quality products and services. The external provider will identify required training/ competence of employees and assure requirements are met.

## **Communication**

External provider shall notify In Tolerance Contract Manufacturing of any changes to processes, products or services including changes of their external providers and where required, obtain approval from In Tolerance. Any changes in Top Management structure as well as QMS system changes must be communicated to In Tolerance.

External provider must ensure that all personnel working on any process, service or product for In Tolerance are aware of their contribution to product conformity, product safety and the importance of ethical behavior.

In tolerance is committed to conducting its business with the highest standards of ethics and in accordance with the laws of the United States and other countries in which it operates, and all who conduct business with In Tolerance are expected to operate in the same manner and with the highest standards of integrity. In Tolerance's further expectation is that our external providers have or will promptly develop and adhere to a code of business conduct. An external provider, its personnel, and its sub-tier providers shall immediately notify In Tolerance of any instance in which it believes that ethical standards of business conduct or any law may have been violated in the performance of work for In Tolerance.

## **Record Retention**

- External providers must have process for record storage, retention and retrieval.
- External provider shall not destroy any records pertinent to product or process supplied to In Tolerance Contract Manufacturing without first providing the opportunity to retain the records and obtaining written permission for destruction.
- Cloud servers used to store records need to be ITAR compliant.
- Records must be controlled indefinitely
- Any parts/ process for Rockwell Collins must have inspection and test records retained for 99+ years.

## **Nonconforming Product**

The external provider shall notify In Tolerance promptly (within 24 hours) of discovery of any nonconformity affecting any product, process or service already delivered and obtain approval for disposition. Notification shall include a clear description of the discrepancy; parts affected, quantity, and delivery date (s). External provider shall support In Tolerance Contract Manufacturing with additional data, and parts if necessary per contract, to resolve customer concerns.

In Tolerance may request a Corrective Action request if discrepant material is received. The external provider is responsible for completing root cause and corrective action by the due date on CA form.

### **Inspection**

In Tolerance Contract Manufacturing inspections shall not absolve the external provider of responsibility to provide conforming product. All inspections of incoming product/ services to In Tolerance Contract Manufacturing are the external provider's responsibility. The external provider will be responsible for monitoring of any special requirements, critical items, or key characteristics indicated by In Tolerance. The use of statistical techniques for product acceptance and related instructions may be used for acceptance when indicated on inspection instructions. The external provider shall retain inspection and test records, and records that pertain to purchasing, production control, manufacturing and any other related documents.

A first article inspection may be requested from In Tolerance when the following occurs:

- 1<sup>st</sup> production run for In Tolerance
- A change in design characteristics affecting form, fit and function
- A change in manufacturing source, process, inspection method, location of manufacture, tooling or materials that could potentially affect form, fit and function
  
- Note: The external provider shall clearly identify and return parts that are deemed damaged or unacceptable to IN Tolerance, regardless of where/ who caused.

### **Right of Access**

The external provider and processor shall provide access for In Tolerance Contract Manufacturing personnel, government and civil aviation authorities, and customers to their facilities, personnel and all applicable documented information when requested as required for quality and management system reviews, product/ process validation evaluations, or investigations.

### **Counterfeit Goods**

Counterfeit Goods are defined as goods or components that:

- Are an unauthorized copies or substitute of an Original Equipment Manufacturer (OEM) item.
- Are not traceable to an OEM sufficient to ensure authenticity in OEM design and manufacture.
- Do not contain proper external or internal materials or components required by the OEM or not constructed in accordance with OEM design.
- Have been reworked, remarked, relabeled, repaired, refurbished, or otherwise modified from OEM design but not disclosed as such or are represented as OEM authentic or new.
- Have not passed all OEM required testing, verification, screening, and quality control processes.

In Tolerance Contract Manufacturing external providers/ sub external providers will take appropriate measures to prevent the delivery of goods containing counterfeit parts/ components or materials including:

For parts/ components, procurement from:

- The OEM
- OEM authorized external provider (must have OEM cert)
- Customer directed source
- External provider that can provide:
  - OEM certs
  - Sufficient records providing unbroken supply chain traceability to the OEM
  - Test and inspection records demonstrating the item's authenticity.
  - Note: Material certs will be available for all parts/ components/ services.  
External provider is responsible for verifying chemistry of material certs.

For raw material, verification to requirements provided on the material certs.

For commercial off the shelf (COTS), verification to requirements on the Certificate of Conformance.

If In Tolerance Contract Manufacturing external providers and/ or sub-external providers become aware of counterfeit goods, Control of Nonconforming Material Procedure will be followed including potential disclosure to the customer.

### **Foreign Object Debris/ Damage**

External provider will maintain a FOD program that is compliant with NAS 412 Foreign Object Damage/ Foreign Object Debris (FOD) Prevention.

### **Identification and Traceability**

- The parts must be identified with a lot/ serial number and date of manufacture. The traceability number must be on the shipping paperwork and traceable back to external provider's production and product conformity.
- The external provider shall retain evidence to document that items furnished under this contract conform to contract requirements. Evidence will generally include information tracing the items back to the manufacturing source of its authorized distributor. At a minimum, evidence shall be sufficient to establish the identity of the item, its manufacturing source, and conformance to the item description. Documentation will be kept indefinitely.

### **Parts Packaging and Preservation**

Parts must be packaged, stored and shipped in a manner to prevent damage and preserves product conformity.