

- d. determine the verification, or other activities, necessary to ensure that the externally provided processes, products, and services meet requirements.

Verification activities of externally provided processes, products, and services shall be performed according to the risks identified by the organization. These shall include inspection or periodic testing, as applicable, when there is high risk of nonconformities including counterfeit parts.

NOTE 1: Customer verification activities performed at any level of the supply chain does not absolve the organization of its responsibility to provide acceptable processes, products, and services and to comply with all requirements.

NOTE 2: Verification activities can include:

- **review of objective evidence of the conformity of the processes, products, and services from the external provider (e.g., accompanying documentation, certificate of conformity, test documentation, statistical documentation, process control documentation, results of production process verification and assessment of changes to the production process thereafter);**
- **inspection and audit at the external provider's premises;**
- **review of the required documentation;**
- **review of production part approval process data;**
- **inspection of products or verification of services upon receipt;**
- **review of delegations of product verification to the external provider.**

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.

When the organization delegates verification activities to the external provider, the scope and requirements for delegation shall be defined and a register of delegations shall be maintained. The organization shall periodically monitor the external provider's delegated verification activities.

When external provider test reports are utilized to verify externally provided products, the organization shall implement a process to evaluate the data in the test reports to confirm that the product meets requirements. When a customer or organization has identified raw material as a significant operational risk (e.g., critical items), the organization shall implement a process to validate the accuracy of test reports.

8.4.3 Information for External Providers

The organization shall ensure the adequacy of requirements prior to their communication to the external provider.

The organization shall communicate to external providers its requirements for:

- a. the processes, products, and services to be provided **including the identification of relevant technical data (e.g., specifications, drawings, process requirements, work instructions);**
- b. the approval of:
 1. products and services;
 2. methods, processes, and equipment;
 3. the release of products and services;

- c. competence, including any required qualification of persons;
- d. the external providers' interactions with the organization;
- e. control and monitoring of the external providers' performance to be applied by the organization;
- f. verification or validation activities that the organization, or its customer, intends to perform at the external providers' premises;
- g. design and development control;**
- h. special requirements, critical items, or key characteristics;**
- i. test, inspection, and verification (including production process verification);**
- j. the use of statistical techniques for product acceptance and related instructions for acceptance by the organization;**
- k. the need to:**
 - **implement a quality management system;**
 - **use customer-designated or approved external providers, including process sources (e.g., special processes);**
 - **notify the organization of nonconforming processes, products, or services and obtain approval for their disposition;**
 - **prevent the use of counterfeit parts (see 8.1.4);**
 - **notify the organization of changes to processes, products, or services, including changes of their external providers or location of manufacture, and obtain the organization's approval;**
 - **flow down to external providers applicable requirements including customer requirements;**
 - **provide test specimens for design approval, inspection/verification, investigation, or auditing;**
 - **retain documented information, including retention periods and disposition requirements;**
- l. the right of access by the organization, their customer, and regulatory authorities to the applicable areas of facilities and to applicable documented information, at any level of the supply chain;**
- m. ensuring that persons are aware of:**
 - **their contribution to product or service conformity;**
 - **their contribution to product safety;**
 - **the importance of ethical behavior.**

8.5 Production and Service Provision

8.5.1 Control of Production and Service Provision

The organization shall implement production and service provision under controlled conditions.