## 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;
- I. 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.