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.