

7.4 Purchasing

7.4.1 Purchasing process

The organization shall document procedures (see 4.2.4) to ensure that purchased product conforms to specified purchasing information.

The organization shall establish criteria for the evaluation and selection of suppliers. The criteria shall be:

- a) based on the supplier's ability to provide product that meets the organization's requirements;
- b) based on the performance of the supplier;
- c) based on the effect of the purchased product on the quality of the medical device;
- d) proportionate to the risk associated with the medical device.

The organization shall plan the monitoring and re-evaluation of suppliers. Supplier performance in meeting requirements for the purchased product shall be monitored. The results of the monitoring shall provide an input into the supplier re-evaluation process.

Non-fulfilment of purchasing requirements shall be addressed with the supplier proportionate to the risk associated with the purchased product and compliance with applicable regulatory requirements.

Records of the results of evaluation, selection, monitoring and re-evaluation of supplier capability or performance and any necessary actions arising from these activities shall be maintained (see 4.2.5).

7.4.2 Purchasing information

Purchasing information shall describe or reference the product to be purchased, including as appropriate:

- a) product specifications;
- b) requirements for product acceptance, procedures, processes and equipment;
- c) requirements for qualification of supplier personnel;
- d) quality management system requirements.

The organization shall ensure the adequacy of specified purchasing requirements prior to their communication to the supplier.

Purchasing information shall include, as applicable, a written agreement that the supplier notify the organization of changes in the purchased product prior to implementation of any changes that affect the ability of the purchased product to meet specified purchase requirements.

To the extent required for traceability given in 7.5.9, the organization shall maintain relevant purchasing information in the form of documents (see 4.2.4) and records (see 4.2.5).

7.4.3 Verification of purchased product

The organization shall establish and implement the inspection or other activities necessary for ensuring that purchased product meets specified purchasing requirements. The extent of verification activities shall be based on the supplier evaluation results and proportionate to the risks associated with the purchased product.

When the organization becomes aware of any changes to the purchased product, the organization shall determine whether these changes affect the product realization process or the medical device.

When the organization or its customer intends to perform verification at the supplier's premises, the organization shall state the intended verification activities and method of product release in the purchasing information.

Records of the verification shall be maintained (see [4.2.5](#)).

7.5 Production and service provision

7.5.1 Control of production and service provision

Production and service provision shall be planned, carried out, monitored and controlled to ensure that product conforms to specification. As appropriate, production controls shall include but are not limited to:

- a) documentation of procedures and methods for the control of production (see [4.2.4](#));
- b) qualification of infrastructure;
- c) implementation of monitoring and measurement of process parameters and product characteristics;
- d) availability and use of monitoring and measuring equipment;
- e) implementation of defined operations for labelling and packaging;
- f) implementation of product release, delivery and post-delivery activities.

The organization shall establish and maintain a record (see [4.2.5](#)) for each medical device or batch of medical devices that provides traceability to the extent specified in [7.5.9](#) and identifies the amount manufactured and amount approved for distribution. The record shall be verified and approved.

7.5.2 Cleanliness of product

The organization shall document requirements for cleanliness of product or contamination control of product if:

- a) product is cleaned by the organization prior to sterilization or its use;
- b) product is supplied non-sterile and is to be subjected to a cleaning process prior to sterilization or its use;
- c) product cannot be cleaned prior to sterilization or its use, and its cleanliness is of significance in use;
- d) product is supplied to be used non-sterile, and its cleanliness is of significance in use;
- e) process agents are to be removed from product during manufacture.

If product is cleaned in accordance with a) or b) above, the requirements contained in [6.4.1](#) do not apply prior to the cleaning process.

7.5.3 Installation activities

The organization shall document requirements for medical device installation and acceptance criteria for verification of installation, as appropriate.

If the agreed customer requirements allow installation of the medical device to be performed by an external party other than the organization or its supplier, the organization shall provide documented requirements for medical device installation and verification of installation.

Records of medical device installation and verification of installation performed by the organization or its supplier shall be maintained (see [4.2.5](#)).