
4.8 **Obtaining Materials, Services, and Cellular Therapy Products**

The facility shall establish and maintain policies, processes, and procedures to ensure that purchased, donated, or otherwise acquired materials, services, or cellular therapy products conform to specified requirements.

4.8.1 Evaluation and Qualification of Suppliers of Materials and Services

The facility shall ensure that suppliers of critical materials or services are qualified and selected based on the supplier's ability to meet specified requirements, including the following:

- 1) Ensure that training and qualifications of personnel who perform activities related to the provision of materials and/or services are addressed.
- 2) Ensure that facilities providing tests or manufacturing services required by these *CT Standards* shall be accredited by AABB or another accrediting body. Standard 5.12.2.10 applies.

- 4.8.1.1** The facility shall review package inserts for all infectious disease test reagents and kits to verify acceptability of use.

4.8.2 Evaluation and Qualification of Suppliers of Cellular Therapy Products

The facility shall ensure that suppliers of cellular therapy products are qualified and selected based on the facility's ability to meet the following requirements:

- 1) Ensure that the source facility is authorized, designated, licensed, registered, and/or accredited.

- 2) Ensure that specified product procurement requirements are met when these activities are performed by a supplier.
- 3) Ensure that training and qualifications of personnel who perform activities related to the supply of cellular therapy products are addressed.
- 4) Ensure that facilities providing cellular therapy products are accredited by AABB or another accrediting body.



4.8.3 Monitoring of Suppliers of Materials, Services, and Cellular Therapy Products

The facility shall:

- 1) Monitor the performance of critical suppliers as needed based on the nature of the material, service, or product and the impact on the quality of the cellular therapy product.
- 2) Take corrective action and report to management when a supplier fails to meet specified requirements. Standard 9.1 applies.



4.8.4 Notification

The agreement between the receiving facility and the supplier shall include a process to notify the shipping facility and the manufacturer (if applicable) when materials are received in an unacceptable condition. Chapter 7, Deviations, Nonconforming Products or Services, and Adverse Events, applies.

Reference Standard 4.5A—Donor Informed Consent or Authorization

The informed consent process for donors or their legally authorized representative shall include an explanation, in understandable terms, to the consentor(s), of any applicable risks, discomforts, benefits, and alternatives. Elements of informed consent shall include the following:

I. General Informed Consent Requirements

- A. Description of participation, including:
 - 1. The consentor's rights as a donor and, where applicable, as a research subject.
 - 2. Cellular procurement procedure, including, but not limited to, risks associated with procurement and side effects of growth factors and/or other pharmacologic agents, if applicable.
 - 3. General explanation of the indications for and expected outcome of cellular procurement, including the possibility of future product procurement, if applicable.
 - 4. Sample procurement and storage for possible future testing.
 - 5. Sample storage, in-vitro manipulation, and analysis.
 - 6. Testing for infectious diseases and genetic disorders or other conditions, as indicated.
 - 7. Notification of abnormal test results.
 - 8. Review of medical history.
 - 9. Review of medical records.
 - 10. Description of confidentiality, including the need for disclosure to other entities of personal and family health information that might affect the intended recipient.
 - 11. Ownership, transfer, and/or disposition of the cellular therapy product.
- B. The consentor(s) shall acknowledge in writing that he or she has received information concerning the risks, benefits, dis-

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