

 F7.2 Control of Nonconforming Products or Services

The facility shall establish and maintain policies, processes, and procedures to prevent the unintended use or release of nonconforming materials, products, or services. This control shall provide for identification, documentation, evaluation, segregation (when appropriate), and disposition of nonconforming materials and products.

7.2.1 Customer Notification

The facility shall report to the customer:

- 1) Any cellular therapy products lost, damaged, or otherwise unsuitable for use.
- 2) Released products or delivered services that are determined to be nonconforming, as soon as possible.

7.2.2 Review and Disposition of Nonconforming Products and Services

Authority for determining disposition of nonconforming products and review of nonconforming services shall be defined.

7.2.2.1 A nonconforming material or product shall be handled in one of the following ways:

- 1) Reworked to meet the specified requirements.
- 2) Accepted by the customer, after disclosure of the nonconformance.
- 3) Relabeled, in conformance with applicable requirements.
- 4) Destroyed.

 F 7.2.2.2 Authorized Release of Nonconforming Products

A nonconforming product shall be released by exception only when there is a docu-

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mented clinical need for the product and when approved by the medical director.

- 7.2.2.2.1** The following are required:
- 1) Notification to the recipient's physician of the out-of-specification or nonconforming values or results.
 - 2) Documentation of the recipient's physician's approval for use of the product. Standard 5.25.1 applies.

7.2.3 **Microbially Contaminated Products**



The facility shall have policies, processes, and procedures addressing the management of cellular therapy products with positive microbial culture results, including:

- 1) Product labeling.
- 2) Investigation of cause.
- 3) Notification of other facilities and/or departments involved in procurement, processing, and distribution of the product.
- 4) Notification of the donor's physician, if it affects the donor's health.
- 5) Notification of recipient's physician.
- 6) Recipient follow-up and outcome analysis.
- 7) Reporting to regulatory agencies, if appropriate.

7.3 **Adverse Events**



- 7.3.1** The procurement facility shall have a process to detect, monitor, evaluate, manage, and report donor adverse events.

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-  **F 7.3.2** The clinical facility shall have a process to detect, monitor, evaluate, manage, and report recipient adverse events related to the cellular therapy.
 -  **F 7.3.3** The processing facility shall have a process to evaluate reported adverse events.
 - 7.3.4** Records of adverse events and the related investigations, evaluations, and notifications shall be maintained.
 - 7.3.5** Investigation results and analysis shall be communicated among all facilities involved in the procurement, processing, and administration, as appropriate.

7.4 Reporting

Reporting of deviations, nonconforming products, and adverse events shall be in accordance with the facility's policies, these *CT Standards*, and applicable laws and regulations.