

§ 1271.250

21 CFR Ch. I (4-1-06 Edition)

and tests, you must validate and approve the process according to established procedures. The validation activities and results must be documented, including the date and signature of the individual(s) approving the validation.

(b) *Written representation.* Any written representation that your processing methods reduce the risk of transmission of communicable disease by an HCT/P, including but not limited to, a representation of sterility or pathogen inactivation of an HCT/P, must be based on a fully verified or validated process.

(c) *Changes.* When changes to a validated process subject to paragraph (a) of this section occur, you must review and evaluate the process and perform revalidation where appropriate. You must document these activities.

§ 1271.250 Labeling controls.

(a) *General.* You must establish and maintain procedures to control the labeling of HCT/Ps. You must design these procedures to ensure proper HCT/P identification and to prevent mix-ups.

(b) *Verification.* Procedures must include verification of label accuracy, legibility, and integrity.

(c) *Labeling requirements.* Procedures must ensure that each HCT/P is labeled in accordance with all applicable labeling requirements, including those in §§ 1271.55, 1271.60, 1271.65, 1271.90, 1271.290, and 1271.370, and that each HCT/P made available for distribution is accompanied by documentation of the donor eligibility determination as required under § 1271.55.

§ 1271.260 Storage.

(a) *Control of storage areas.* You must control your storage areas and stock rooms to prevent:

(1) Mix-ups, contamination, and cross-contamination of HCT/Ps, supplies, and reagents, and

(2) An HCT/P from being improperly made available for distribution.

(b) *Temperature.* You must store HCT/Ps at an appropriate temperature.

(c) *Expiration date.* Where appropriate, you must assign an expiration date to each HCT/P based on the following factors:

(1) HCT/P type;

(2) Processing, including the method of preservation;

(3) Storage conditions; and

(4) Packaging.

(d) *Corrective action.* You must take and document corrective action whenever proper storage conditions are not met.

(e) *Acceptable temperature limits.* You must establish acceptable temperature limits for storage of HCT/Ps at each step of the manufacturing process to inhibit the growth of infectious agents. You must maintain and record storage temperatures for HCT/Ps. You must periodically review recorded temperatures to ensure that temperatures have been within acceptable limits.

§ 1271.265 Receipt, predistribution shipment, and distribution of an HCT/P.

(a) *Receipt.* You must evaluate each incoming HCT/P for the presence and significance of microorganisms and inspect for damage and contamination. You must determine whether to accept, reject, or place in quarantine each incoming HCT/P, based upon pre-established criteria designed to prevent communicable disease transmission.

(b) *Predistribution shipment.* If you ship an HCT/P within your establishment or between establishments (e.g., procurer to processor) and the HCT/P is not available for distribution as described in paragraph (c) of this section, you must first determine and document whether pre-established criteria designed to prevent communicable disease transmission have been met, and you must ship the HCT/P in quarantine.

(c) *Availability for distribution.* (1) Before making an HCT/P available for distribution, you must review manufacturing and tracking records pertaining to the HCT/P, and, on the basis of that record review, you must verify and document that the release criteria have been met. A responsible person must document and date the determination that an HCT/P is available for distribution.

(2) You must not make available for distribution an HCT/P that is in quarantine, is contaminated, is recovered from a donor who has been determined