

photocopies, microfiche, or microfilm. Equipment that is necessary to make the records available and legible, such as computer and reader equipment, must be readily available. Records stored in electronic systems must be backed up.

(d) *Length of retention.* You must retain all records for 10 years after their creation, unless stated otherwise in this part. However, you must retain the records pertaining to a particular HCT/P at least 10 years after the date of its administration, or if the date of administration is not known, then at least 10 years after the date of the HCT/Ps distribution, disposition, or expiration, whichever is latest. You must retain records for archived specimens of dura mater for 10 years after the appropriate disposition of the specimens.

(e) *Contracts and agreements.* You must maintain the name and address and a list of the responsibilities of any establishment that performs a manufacturing step for you. This information must be available during an inspection conducted under § 1271.400.

§ 1271.290 Tracking.

(a) *General.* If you perform any step in the manufacture of an HCT/P in which you handle the HCT/P, you must track each such HCT/P in accordance with this section, to facilitate the investigation of actual or suspected transmission of communicable disease and take appropriate and timely corrective action.

(b) *System of HCT/P tracking.* (1) You must establish and maintain a system of HCT/P tracking that enables the tracking of all HCT/Ps from:

- (i) The donor to the consignee or final disposition; and
- (ii) The consignee or final disposition to the donor.

(2) Alternatively, if you are an establishment that performs some but not all of the steps in the manufacture of an HCT/P in which you handle the HCT/P, you may participate in a system of HCT/P tracking established and maintained by another establishment responsible for other steps in the manufacture of the same HCT/P, provided that the tracking system complies with all the requirements of this section.

(c) *Distinct identification code.* As part of your tracking system, you must ensure: That each HCT/P that you manufacture is assigned and labeled with a distinct identification code, e.g., alphanumeric, that relates the HCT/P to the donor and to all records pertaining to the HCT/P; and that labeling includes information designed to facilitate effective tracking, using the distinct identification code, from the donor to the recipient and from the recipient to the donor. Except as described in § 1271.55(a)(1), you must create such a code specifically for tracking, and it may not include an individual's name, social security number, or medical record number. You may adopt a distinct identification code assigned by another establishment engaged in the manufacturing process, or you may assign a new code. If you assign a new code to an HCT/P, you must establish and maintain procedures for relating the new code to the old code.

(d) *Tracking from consignee to donor.* As part of your tracking system, you must establish and maintain a method for recording the distinct identification code and type of each HCT/P distributed to a consignee to enable tracking from the consignee to the donor.

(e) *Tracking from donor to consignee or final disposition.* As part of your tracking system, you must establish and maintain a method for documenting the disposition of each of your HCT/Ps, to enable tracking from the donor to the consignee or final disposition. The information you maintain must permit the prompt identification of the consignee of the HCT/P, if any.

(f) *Consignees.* At or before the time of distribution of an HCT/P to a consignee, you must inform the consignee in writing of the requirements in this section and of the tracking system that you have established and are maintaining to comply with these requirements.

(g) *Requirements specific to dura mater donors.* You must archive appropriate specimens from each donor of dura mater, under appropriate storage conditions, and for the appropriate duration, to enable testing of the archived material for evidence of transmissible

spongiform encephalopathy, and to enable appropriate disposition of any affected nonadministered dura mater tissue, if necessary.

[69 FR 68681, Nov. 24, 2004, as amended at 70 FR 29952, May 25, 2005]

§ 1271.320 Complaint file.

(a) *Procedures.* You must establish and maintain procedures for the review, evaluation, and documentation of complaints as defined in §1271.3(aa), relating to core current good tissue practice (CGTP) requirements, and the investigation of complaints as appropriate.

(b) *Complaint file.* You must maintain a record of complaints that you receive in a file designated for complaints. The complaint file must contain sufficient information about each complaint for proper review and evaluation of the complaint (including the distinct identification code of the HCT/P that is the subject of the complaint) and for determining whether the complaint is an isolated event or represents a trend. You must make the complaint file available for review and copying upon request from FDA.

(c) *Review and evaluation of complaints.* You must review and evaluate each complaint relating to core CGTP requirements to determine if the complaint is related to an HCT/P deviation or to an adverse reaction, and to determine if a report under §1271.350 or another applicable regulation is required. As soon as practical, you must review, evaluate, and investigate each complaint that represents an event required to be reported to FDA, as described in §1271.350. You must review and evaluate a complaint relating to core CGTP requirements that does not represent an event required to be reported to determine whether an investigation is necessary; an investigation may include referring a copy of the complaint to another establishment that performed manufacturing steps pertinent to the complaint. When no investigation is made, you must maintain a record that includes the reason no investigation was made, and the name of the individual(s) responsible for the decision not to investigate.

Subpart E—Additional Requirements for Establishments Described in § 1271.10

SOURCE: 69 FR 68686, Nov. 24, 2004, unless otherwise noted.

§ 1271.330 Applicability.

The provisions set forth in this subpart are being implemented for non-reproductive HCT/Ps described in §1271.10 and regulated solely under section 361 of the Public Health Service Act and the regulations in this part, and for the establishments that manufacture those HCT/Ps. HCT/Ps that are drugs or devices regulated under the act, or are biological products regulated under section 351 of the Public Health Service Act, are not subject to the regulations set forth in this subpart.

§ 1271.350 Reporting.

(a) *Adverse reaction reports.* (1) You must investigate any adverse reaction involving a communicable disease related to an HCT/P that you made available for distribution. You must report to FDA an adverse reaction involving a communicable disease if it:

- (i) Is fatal;
- (ii) Is life-threatening;
- (iii) Results in permanent impairment of a body function or permanent damage to body structure; or
- (iv) Necessitates medical or surgical intervention, including hospitalization.

(2) You must submit each report on a Form FDA-3500A to the address in paragraph (a)(5) of this section within 15 calendar days of initial receipt of the information.

(3) You must, as soon as practical, investigate all adverse reactions that are the subject of these 15-day reports and must submit followup reports within 15 calendar days of the receipt of new information or as requested by FDA. If additional information is not obtainable, a followup report may be required that describes briefly the steps taken to seek additional information and the reasons why it could not be obtained.

(4) You may obtain copies of the reporting form (FDA-3500A) from the Center for Biologics Evaluation and Research (see address in paragraph