

## § 1271.145

## 21 CFR Ch. I (4–1–06 Edition)

(A) The presence of relevant communicable disease agents and/or

(B) Risk factors for or clinical evidence of relevant communicable disease agents or diseases.

(4) With the Biohazard legend shown in §1271.3(h), if the results of any screening or testing performed indicate:

(i) The presence of relevant communicable disease agents and/or

(ii) Risk factors for or clinical evidence of relevant communicable disease agents or diseases.

(5) “WARNING: Reactive test results for (name of disease agent or disease),” in the case of reactive test results.

(6) “Advise recipient that screening and testing of the donor(s) were not performed at the time of cryopreservation of the reproductive cells or tissue, but have been performed subsequently,” for paragraphs (a)(3) or (a)(4) of this section.

[69 FR 29830, May 25, 2004, as amended at 70 FR 29952, May 25, 2005]

### Subpart D—Current Good Tissue Practice

SOURCE: 69 FR 68681, Nov. 24, 2004, unless otherwise noted.

#### § 1271.145 Prevention of the introduction, transmission, or spread of communicable diseases.

You must recover, process, store, label, package, and distribute HCT/Ps, and screen and test cell and tissue donors, in a way that prevents the introduction, transmission, or spread of communicable diseases.

#### § 1271.150 Current good tissue practice requirements.

(a) *General.* This subpart D and subpart C of this part set forth current good tissue practice (CGTP) requirements. You must follow CGTP requirements to prevent the introduction, transmission, or spread of communicable diseases by HCT/Ps (e.g., by ensuring that the HCT/Ps do not contain communicable disease agents, that they are not contaminated, and that they do not become contaminated during manufacturing). Communicable diseases include, but are not limited to, those transmitted by viruses, bacteria,

fungi, parasites, and transmissible spongiform encephalopathy agents. CGTP requirements govern the methods used in, and the facilities and controls used for, the manufacture of HCT/Ps, including but not limited to all steps in recovery, donor screening, donor testing, processing, storage, labeling, packaging, and distribution. The CGTP provisions specifically governing determinations of donor eligibility, including donor screening and testing, are set out separately in subpart C of this part.

(b) *Core CGTP requirements.* The following are core CGTP requirements:

(1) Requirements relating to facilities in §1271.190(a) and (b);

(2) Requirements relating to environmental control in §1271.195(a);

(3) Requirements relating to equipment in §1271.200(a);

(4) Requirements relating to supplies and reagents in §1271.210(a) and (b);

(5) Requirements relating to recovery in §1271.215;

(6) Requirements relating to processing and process controls in §1271.220;

(7) Requirements relating to labeling controls in §1271.250(a) and (b);

(8) Requirements relating to storage in §1271.260 (a) through (d);

(9) Requirements relating to receipt, predistribution shipment, and distribution of an HCT/P in §1271.265(a) through (d); and

(10) Requirements relating to donor eligibility determinations, donor screening, and donor testing in §§1271.50, 1271.75, 1271.80, and 1271.85.

(c) *Compliance with applicable requirements*—(1) *Manufacturing arrangements*

(i) If you are an establishment that engages in only some operations subject to the regulations in this subpart and subpart C of this part, and not others, then you need only comply with those requirements applicable to the operations that you perform.

(ii) If you engage another establishment (e.g., a laboratory to perform communicable disease testing, or an irradiation facility to perform terminal sterilization), under a contract, agreement, or other arrangement, to perform any step in manufacture for you, that establishment is responsible for complying with requirements applicable to that manufacturing step.