to be ineligible or for whom a donor-
eligibility determination has not been
completed (except as provided under
§§ 1271.60, 1271.65, and 1271.90), or that
otherwise does not meet release cri-
teria designed to prevent commu-
nicable disease transmission.
(3) You must not make available for
distribution any HCT/P manufactured
under a departure from a procedure rel-
vant to preventing risks of commu-
nicable disease transmission, unless a
responsible person has determined that
the departure does not increase the
risk of communicable disease through
the use of the HCT/P. You must record
and justify any departure from a proce-
dure at the time of its occurrence.
(d) Packaging and shipping. Packaging
and shipping containers must be de-
signed and constructed to protect the
HCT/P from contamination. For each
type of HCT/P, you must establish ap-
nropriate shipping conditions to be
maintained during transit.
(e) Procedures. You must establish
and maintain procedures, including re-
lease criteria, for the activities in
paragraphs (a) through (d) of this sec-
tion. You must document these activi-
ties. Documentation must include:
(1) Identification of the HCT/P and
the establishment that supplied the
HCT/P;
(2) Activities performed and the re-
sults of each activity;
(3) Date(s) of activity;
(4) Quantity of HCT/P subject to the
activity; and
(5) Disposition of the HCT/P (e.g.,
identity of consignee).
(f) Return to inventory. You must es-
ablish and maintain procedures to de-
termine if an HCT/P that is returned to
your establishment is suitable to be re-
turned to inventory.
§ 1271.270 Records.
(a) General. You must maintain
records concurrently with the perfor-
manve of each step required in this sub-
part and subpart C of this part. Any re-
quirement in this part that an action
be documented involves the creation of
a record, which is subject to the re-
quirements of this section. All records
must be accurate, indelible, and leg-
ible. The records must identify the per-
sion performing the work and the dates
of the various entries, and must be as
detailed as necessary to provide a com-
plete history of the work performed
and to relate the records to the par-
ticular HCT/P involved.
(b) Records management system. You
must establish and maintain a records
management system relating to core
CGTP requirements. Under this sys-
tem, records pertaining to a particular
HCT/P must be maintained in such a
way as to facilitate review of the HCT/
P's history before making it available
distribution and, if necessary, sub-
sequent to the HCT/Ps release as part
of a followup evaluation or investiga-
tion. Records pertinent to the manu-
facture of HCT/Ps (e.g., labeling and
packaging procedures, and equipment
logs) must also be maintained and or-
ganized under the records management
system. If records are maintained in
more than one location, then the
records management system must be
designed to ensure prompt identifica-
tion, location, and retrieval of all
records.
(c) Methods of retention. You may
maintain records required under this
subpart electronically, as original
paper records, or as true copies such as
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 re-
tain 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 ex-
piration, whichever is latest. You must
retain records for archived specimens
of dura mater for 10 years after the ap-
propriate 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 manu-
factoring step for you. This informa-
tion must be available during an in-
spection conducted under §1271.400.