§ 610.47 Hepatitis C virus (HCV) “lookback” requirements.

(a) If you are an establishment that collects Whole Blood or blood components, including Source Plasma and Source Leukocytes, you must establish, maintain, and follow an appropriate system for the following actions:

(1) Within 3 calendar days after a donor tests reactive for evidence of hepatitis C virus (HCV) infection when tested under § 610.40(a) and (b) of this chapter or when you are made aware of other reliable test results or information indicating evidence of HCV infection, you must review all records required under § 606.160(d) of this chapter, to identify blood and blood components previously donated by such a donor. For those identified blood and blood components collected:

(i) Twelve months and less before the donor’s most recent nonreactive screening tests, or

(ii) Twelve months and less before the donor’s reactive direct viral detection test, e.g., nucleic acid test and nonreactive antibody screening test, whichever is the lesser period, you must:

(A) Quarantine all previously collected in-date blood and blood components identified under paragraph (a)(1) of this section if intended for use in another person or for further manufacture into injectable products, except pooled blood components intended solely for further manufacturing into products that are manufactured using validated viral clearance procedures; and

(B) Notify consignees to quarantine all previously collected in-date blood and blood components identified under paragraph (a)(1) of this section if intended for use in another person or for further manufacture into injectable products, except pooled blood components intended solely for further manufacturing into products that are manufactured using validated viral clearance procedures, when notified by the collecting establishment.

(2) You must perform a supplemental (additional, more specific) test for HCV as required under § 610.40(e) on the reactive donation.

(3) You must notify consignees of the supplemental (additional, more specific) test results for HCV, or the results of the reactive screening test if there is no available supplemental test that is approved for such use by FDA, or if under an investigational new drug application (IND) or investigational device exemption (IDE), is exempted for such use by FDA, within 45 calendar days after the donor tests reactive for evidence of HCV infection under § 610.40(a) and (b). Notification of consignees must include the test results for blood and blood components identified under paragraph (a)(1) of this section that were previously collected from donors who later test reactive for evidence of HCV infection.

(4) You must release from quarantine, destroy, or relabel quarantined in-date blood and blood components consistent with the results of the supplemental (additional, more specific) test performed under paragraph (a)(2) of this section, or the results of the reactive screening test if there is no available supplemental test that is approved for such use by FDA, or if under an IND or IDE, exempted for such use by FDA.

(b) If you are a consignee of Whole Blood or blood components, including Source Plasma or Source Leukocytes, you must establish, maintain, and follow an appropriate system for the following actions:

(1) You must quarantine all previously collected in-date blood and blood components identified under paragraph (a)(1) of this section if intended for use in another person or for further manufacture into injectable products, except pooled blood components intended solely for further manufacturing into products that are manufactured using validated viral clearance procedures, when notified by the collecting establishment.

(2) You must release from quarantine, destroy, or relabel quarantined in-date blood and blood components, consistent with the results of the supplemental (additional, more specific) test performed under paragraph (a)(2)
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of this section, or the results of the re-
active screening test if there is no available supplemental test that is ap-
proved for such use by FDA, or if under
an IND or IDE, is exempted for such
use by FDA.
(3) When the supplemental (ad-
tional, more specific) test for HCV is
positive or when the screening test is
reactive and there is no available sup-
plemental test that is approved for
such use by FDA, or if under an IND or
IDE, is exempted for such use by FDA,
you must notify transfusion recipi-
ents of previous collections of blood
and blood components at increased risk
of transmitting HCV infection, or the
recipient’s physician of record, of the
need for recipient HCV testing and
counseling. You must notify the recipi-
ent’s physician of record or a legal rep-
resentative or relative if the recipient
is a minor, adjudged incompetent by a
State court, or if the recipient is com-
petent but State law permits a legal
representative or relative to receive in-
formation on behalf of the recipient.
You must make reasonable attempts to
perform the notification within 12
weeks after receiving the supplemental
(additional, more specific) test results
for evidence of HCV infection from the
collecting establishment, or after re-
ceiving the donor’s reactive screening
test result for HCV if there is no avail-
able supplemental test that is approved
for such use by FDA, or if under an IND
or IDE, is exempted for such use by FDA.
(c) Actions under this section do not
constitute a recall as defined in §7.3 of
this chapter.

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§ 610.48 Hepatitis C virus (HCV)
“lookback” requirements based on
review of historical testing records.

(i) Review all records of donor testing
for hepatitis C virus (HCV) performed
before February 20, 2008. The review
must include records dating back in-
definitely for computerized electronic
records, and to January 1, 1988, for all
other records. Record review, quar-
tantine, testing, notification, and dis-
position performed before February 20,
2008 that otherwise satisfy the require-
ments under §610.47, are exempt from
this section.
(ii) Identify donors who tested reac-
tive for evidence of HCV infection. Do-
nors who tested reactive by a screening
test and negative by an appropriate
supplemental (additional, more spe-
cific) test under §610.40(e) for evidence
of HCV infection on the same donation
are not subject to further action.
(iii) Identify the blood and blood
components previously collected from
such donors:
(A) Twelve months and less before
the donor’s most recent nonreactive
screening tests, or
(B) Twelve months and less before
the donor’s reactive direct viral detec-
tion test, e.g., nucleic acid test and
nonreactive antibody screening test,
whichever is the lesser period.
(2) If you did not perform a supple-
mental (additional, more specific) test
at the time of the reactive donation,
you may perform a supplemental test
or a licensed screening test with known
greater sensitivity than the test of
record using either a frozen sample
from the same reactive donation or a
fresh sample from the same donor, if
obtainable. If neither is available, pro-
cceed with paragraphs (b)(3), (b)(4), and
(b)(5) of this section.
(3) You must, within 3 calendar days
after identifying the blood and blood
components previously collected from
donors who tested reactive for evidence
of HCV infection:
(1) Quarantine all previously col-
lected in-date blood and blood compo-
nents identified under paragraph
(b)(1)(ii) of this section if intended for
use in another person or for further
manufacture into injectable products,
except pooled components solely in-
tended for further manufacturing into
products that are manufactured using
validated viral clearance procedures.

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