Appendix II.

TABLE 1 (From Reference [27]): Donor Deferral, Product Disposition, Recipient Notification for Whole Blood, Blood Components Intended for Transfusion, Source Leukocytes, and Other Cellular Blood Components Intended for Further Manufacture

Risk	Deferral	Disposition of Product	BPDR (21 CFR 606.171) if previously distributed product	Recipient Tracing/Notification
Diagnosed with vCJD, or suspected vCJD, CJD, or CJD and age <55 years	Permanent	Immediately retrieve, quarantine/notify consignees for all in-date products and all out-of-date cellular blood components intended for manufacturing into injectable products.	Yes	Consignee notified, consignee informs responsible caretaker for discretionary recipient notification, counseling
Risk factors for CJD: Receipt of pituitary-derived growth hormone, or dura mater transplant Family history of CJD in >1 family member	Permanent Indefinite, reentry if genetic testing does not reveal CJD-associated prion protein allele	Immediately retrieve, quarantine/notify consignees for all in-date products and all out-of-date cellular blood components intended for manufacturing into injectable products.	Yes	Consignee notified, consignee informs responsible caretaker for discretionary recipient notification, counseling
CJD in only 1 family member	Indefinite, reentry if genetic testing does not reveal CJD-associated prion protein allele	Immediately retrieve, quarantine/notify consignees for all in-date products and all out-of-date cellular blood components intended for manufacturing into injectable products.	Yes	No

TABLE 1 (From Reference [27]): Continued

Risk	Deferral	Disposition of Product	BPDR (21 CFR 606.171) if previously distributed product	Recipient Tracing/Notification
Phase I Geographic donor deferrals (U.K. ≥3 months 1980-1996; France ≥5 years 1980-present; military in Europe as specified, transfusion in U.K. since 1980)	Indefinite	Immediately retrieve, quarantine/notify consignees for all in-date products and all out-of-date cellular blood components intended for manufacturing into injectable products.	No - if prior to deferral implementation	No
			Yes - if after deferral implementation	
Phase II Geographic donor deferrals (Europe ≥5 years 1980-present)	Indefinite	Collected prior to deferral implementation - No retrieval, quarantine, consignee notification	No - if prior to deferral implementation	No
		Collected after deferral implemented - Immediately retrieve, quarantine/notify consignees for all in-date products and all out-of-date cellular blood components intended for manufacturing into injectable products.	Yes - if after deferral implementation	
Bovine insulin injection	Indefinite, donor reentry if proof of non-U.K. insulin source	Immediately retrieve, quarantine/notify consignees for all in-date products and all out-of-date cellular blood components intended for manufacturing into injectable products.	Yes	No

TABLE 2 (Modified from Reference [27]): Donor Deferral, Product Disposition, and Recipient Notification for Plasma and Plasma Derivatives

Risk	Deferral	Disposition of Product	BPDR (21 CFR 606.171) if previously distributed product	Recipient Tracing/Notification
Phase I Geographic donor deferrals (U.K. ≥3 months 1980-1996; France ≥5 years 1980-present; military in Europe as specified, transfusion in U.K. since 1980)	Indefinite	SP and RP: Collected prior to deferral implementation- No retrieval, quarantine, consignee notification	No - if prior to deferral implementation	No
		SP and RP: Collected after deferral implementation - Immediately retrieve, quarantine, notify consignees of in-date SP and all RP unless known to be previously pooled	Yes- if after deferral implementation	
		PD: No retrieval, quarantine, consignee notification	No	
Phase II Geographic donor deferrals (Europe ≥5 years 1980-present) SP	No deferral	SP: *All phase I deferrals remain in place,* e.g., U.K. ≥ 3 months 1980-1996; France ≥ 5 years 1980-present; military in Europe as specified; transfusion in the U.K. since 1980. There is no Phase II deferral for SP.	Not Applicable	No
Phase II Geographic donor deferrals (Europe ≥5 years 1980-present) RP	Indefinite	RP: Collected prior to deferral implementation- No retrieval, quarantine, consignee notification	No- if collected prior to deferral implementation	
		RP: Collected after deferral implementation: Immediately retrieve, quarantine, notify consignees for all RP unless known to be previously pooled	Yes - if collected after deferral implementation	
		PD: No retrieval, quarantine, consignee notification	No	

Abbreviations: SP, Source Plasma; RP, recovered plasma; PD, plasma derivatives; BPDR, Biological Products Deviation Report

Table 2 (Modified from Reference [27]) Continued

Risk	Deferral	Disposition of Product	BPDR [21 CFR 606.171] if previously distributed product	Recipient Tracing/Notification
Bovine insulin injection	Indefinite, donor reentry if proof of non-U.K. insulin source	SP and RP: Immediately retrieve, quarantine/notify consignees for in-date SP and all RP unless plasma known to be previously pooled PD: No retrieval, quarantine, consignee notification	Yes No	No No
Diagnosed with vCJD, suspected vCJD	Permanent	SP and RP: Immediately retrieve, quarantine/notify consignees for in-date SP and all RP PD: Immediately retrieve, quarantine, notify consignees	Yes Yes	Consignee notified, consignee informs responsible caretaker for discretionary recipient notification, counseling

Abbreviations: SP, Source Plasma; RP, recovered plasma; PD, plasma derivatives; BPDR, Biological Products Deviation Report

Table 2 (Modified from Reference [27]) Continued

Risk	Deferral	Disposition of Product	BPDR (21 CFR 606.171) if previously distributed product	Recipient Tracing/Notification
Diagnosed with CJD and age <55 years	Permanent	SP and RP: Disposition decided case-by-case depending upon investigation results PD: Disposition decided case-by-case depending upon investigation results	Yes Decided upon case-by-case	Case-by-case recommendation, depending upon investigation results
Diagnosed with CJD (and age ≥55 years)	Permanent	SP and RP: Immediately retrieve, quarantine/notify consignees for in-date SP and all RP unless known to be previously pooled PD: No retrieval, quarantine, consignee notification	Yes No	No No
Risk factors for CJD: Receipt of pituitary-d growth hormone, or d mater transplant Family history of CJD family member	Permanent Indefinite	SP and RP: Immediately retrieve, quarantine/notify consignees for in-date SP and all RP unless known to be previously pooled PD: No retrieval, quarantine, consignee notification	Yes No	No No
CJD in only 1 family member	Indefinite; reentry if genetic testing fails to reveal CJD-associated PrP allele	SP and RP: Immediately retrieve, quarantine/notify consignees in-date SP and all RP unless known to be previously pooled PD: No retrieval, quarantine, consignee notification	Yes No	No No

Abbreviations: SP, Source Plasma; RP, recovered plasma; PD, plasma derivatives; BPDR, Biological Products Deviation Report; PrP, prion protein

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