

Contains Nonbinding Recommendations

APPENDIX H: REPORTING CONTRACT CHANGES

Type of Change	Reporting Category			
	PAS	CBE30	CBE	AR
Use of an FDA registered contract facility not previously engaged in blood product testing to perform routine serologic testing and/or infectious disease screening, and supplemental and/or confirmatory testing for blood and blood products. These contract facilities perform the tests of record (tests used to determine donor eligibility/product suitability).	X			
Use of a contract facility that was not previously engaged in performing a manufacturing step on blood products to perform a manufacturing step. This includes, but is not limited to, contract facilities that irradiate blood products or supply Red Blood Cells for immunization.	X			
Expanding operations to include infectious disease test laboratories. Note: Refer to Appendix B for reporting facility changes and Appendix C for handling changes in facility relocations.	X			
Use of an FDA registered off-site contract storage facility to store an unlicensed product collected under a pending supplement or for the storage of excess licensed product that meets all product release criteria.		X		
Use of an FDA registered contract facility currently engaged in performing manufacturing steps on blood products, to perform a specific manufacturing step.			X	
Use of, or change in, a contract testing laboratory that performs reference or quality control testing or tests that are not required or recommended by FDA. Note: This does not include a change in a contract testing laboratory that performs the infectious disease or ABO/Rh tests of record. Such a change must be reported as a CBE. See sections IV.B. and C. of this guidance.				X

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	PAS	CBE30	CBE	AR
Changes in infectious disease tests that are required or recommended by FDA at a previously approved contract testing laboratory. For example: adding an FDA required or recommended test to the testing currently performed by the approved contract testing laboratory.				X
Notification of changes in operations made by an approved contractor, for example, notification by an approved contract testing laboratory that they have changed the contract laboratory they use to perform confirmatory testing.				X
Temporary use of a previously approved alternate or back-up contractor to perform a manufacturing step. Include the dates the alternate contractor was used.				X
Use of, or change in, a contractor to provide personnel responsible for collecting blood products or performing quality assurance activities.				X
Change in address of any unlicensed contractor.				X