

§ 493.1445(e)(13) that the director has to ensure that policies and procedures are established for monitoring employee competency and to identify needs for remedial training or continuing education. Monitoring employee competency may include the evaluation of previously tested specimens as unknowns. However, we are deleting this former requirement at § 493.1265(a)(13) because we believe it is somewhat duplicative of the laboratory director responsibility.

Comment: Three commenters, including a professional organization, recommended that living transplants be deleted from § 493.1265(b)(2) that requires the performance of mixed lymphocyte cultures or other augmented testing to evaluate HLA class II compatibility. The commenters stated that although appropriate for bone marrow transplantation, mixed lymphocyte culture is performed rarely in living-related kidney transplantation where HLA Class II compatibility and genetic linkages can be adequately determined using serological methods. In addition, the commenters maintained that mixed lymphocyte culture tests were unnecessary in solid organ transplants and not considered a contraindication to this type of transplantation.

Response: We agree with the commenters. The phrase, “and living transplants,” formerly at § 493.1265(b)(2), was deleted in a technical correction notice published on January 19, 1993. In addition, we recognize the evolving nature of transplant medicine makes it difficult to prescribe standards for testing protocols that may be quickly outdated with emerging research data and information, for example, graft survival, acute, and chronic rejection. For this reason we are revising the requirements formerly at §§ 493.1265(b) and (c) that specified the type of testing to be performed for each transplant type. We are requiring (now at § 493.1278(f)(1)) that laboratories performing histocompatibility testing for transfusion and transplantation purposes have available, and follow, written policies and protocols specifying the histocompatibility testing to be performed for each type of cell, tissue, or organ to be transfused or transplanted. The laboratory’s policies must address, as applicable, testing protocols for cadaver donor, living, living-related and combined organ and tissue transplants; the level of testing required to support clinical transplant protocols (for example, HLA typing at the antigen or allele level); and any additional testing required for patients at high risk for allograft rejection. In

addition, we believe this less prescriptive, but laboratory-specific requirement provides the flexibility required to ensure laboratory practice that is responsive to advances in transplantation medicine and laboratory methodologies and technology.

Comment: One commenter stated that the requirement, at § 493.1265(b)(3), to provide the results of the final crossmatch before nonrenal solid organ transplantation when the recipient has demonstrated presensitization is not necessarily relevant or realistic for all types of grafts. The commenter cited the short viability time of certain organs (heart and lung) and unpublished data pertaining to the nonrelationship between high-titered positive donor T cell crossmatches and liver allograft survival.

Response: We agree with the commenter that the period of time that organs, for example, the liver, pancreas, and heart remain viable after removal from the donor is often not sufficient for the laboratory to complete the crossmatch. The regulation formerly at § 493.1265(b)(3) (now at § 493.1278(f)(3)) has been revised to require laboratories to develop and follow policies for testing and providing results of final crossmatches when the recipient has demonstrated presensitization by prior serum screening. In addition, the policy must address emergency transplant situations that would not allow time for the laboratory to perform prospective crossmatches. In addition, we would like to clarify that the intent of § 493.1278(f)(3) is not to preclude the use of crossmatch-positive nonrenal organs and tissues but to ensure, whenever possible, the availability of all pertinent test results on which the physician(s) may base their decision to proceed with the transplant.

Section 493.1267 Condition: Clinical Cytogenetics

Specific comments received and response to comments regarding § 493.1267 are set forth below.

Comment: One commenter suggested the cross-references to subpart K at § 493.1267 list only those portions that apply to cytogenetic testing so that, for example, the general requirement for testing positive and negative controls is not referenced. The commenter suggested at the very least, Appendix C (Survey Procedures and Interpretative Guidelines for Laboratories and Laboratory Services) of the State Operations Manual (CMS Pub. 7) should instruct CLIA surveyors to ignore this requirement when inspecting a cytogenetics laboratory.

Response: The task of delineating all applicable requirements of subpart K for each specialty or subspecialty of testing would require continuous revision and updating for new test systems and emerging technologies. For this reason, the requirement (now at § 493.1225) remains unchanged and continues to direct laboratories to comply with the requirements of subpart K that are applicable to the testing being performed. However, Appendix C of the State Operations Manual will give guidance to surveyors concerning the control requirements for clinical cytogenetics. As specified now at § 493.1256(e)(2), each day of use, the laboratory is required to test the positive and negative reactivity of staining materials to ensure predictable staining characteristics. Media must be checked for sterility and to ensure that it supports growth of the appropriate tissues as required now at § 493.1256(e)(4). As for materials to demonstrate chromosome abnormalities, for example, linkage, breakage, or translocation, Appendix C of the State Operations Manual (CMS Pub. 7) states that these materials are not routinely available; however, an alternative procedure for the immediate assessment and monitoring of all testing over time must be instituted by the laboratory as specified now at § 493.1256(h).

Comment: A few commenters stated laboratory testing of sex chromatin by Barr body analysis or by “Y” body analysis is not considered the standard of practice for the diagnosis of individuals with sex chromosome aneuploidy, citing the well documented frequency of mosaicism in individuals with sex chromosome aneuploidy that leads to false negatives. Therefore, they strongly recommend not employing this testing as a screening test and deleting it from the list of tests that are performed in cytogenetics laboratories.

Response: We agree with the commenters and are deleting the requirements pertaining to the performance of X and Y chromatin counts for sex determination that were formerly at § 493.1267(a). In this final rule at § 493.1276(c), we are now requiring full chromosome analysis for sex determination.

Comment: A few commenters questioned the requirement that chromosome resolution be sufficient to support the reported result. One commenter stated that this is a “catch 22” in that a low resolution study reported as normal in a patient with an abnormality only detectable at a higher level of resolution would be wrong, however, the low resolution analysis would be in support of the reported