

- Section 493.1254 now specifies that when using unmodified manufacturer's equipment, instrument or test systems, the laboratory must follow the manufacturer's instructions for maintenance and function check protocols rather than establish its own. While this revision results in a less stringent requirement than that specified under former § 493.1215, we do not anticipate a change (decrease) in burden or costs to the laboratory because following the manufacturer's instructions for maintenance and function checks when using unmodified equipment, instruments, or test systems was acceptable practice for meeting the former requirement.

- In the specialty of histocompatibility now at § 493.1278, the laboratory's reagent typing inventory must indicate reagent specificity as well as the previously required source, bleeding date and identification number, and volume remaining. Indicating a reagent's specificity in the laboratory's reagent inventory is routine laboratory practice that was inadvertently not addressed in the regulations. This new requirement for documentation of reagent specificity will have no impact on the laboratory's burden or costs.

Revisions Resulting in a Decrease in Burden or Costs.

- We are eliminating the requirement under the specialty of histocompatibility for each individual performing testing to evaluate previously tested specimens monthly as specified formerly at § 493.1265. The mechanism for and frequency of competency assessment of histocompatibility testing personnel will now be determined, as it is in all other laboratory specialties and subspecialties, by the laboratory's technical consultant or supervisor under §§ 493.1413(b)(8) and (9) and 493.1449(b)(8) and (9), respectively. Although this is a reduction in burden, we cannot estimate the cost savings.

- For laboratories performing histocompatibility testing, we are eliminating the specified frequencies for screening potential transplant recipient sera for performed HLA-A and B antibodies (formerly at § 493.1265(a)(8)(i)). Instead, in this final rule at § 493.1278(d)(5), we are requiring the laboratory to have available and follow a policy, consistent with clinical transplant protocols, for the frequency of such antibody screening. While this is most likely a reduction in burden, we cannot estimate the cost savings, since emerging data and research information

will be an ongoing factor in determining appropriate screening frequencies.

- For the performance of non-renal transplantation in an emergency situation, we are eliminating the requirement that the results of final crossmatches be available before the transplantation when the recipient demonstrates presensitization by prior serum screening. In this final rule at § 493.1278(f)(3) (formerly at § 493.1265(b)(3)), the laboratory must have available, and follow, policies that address when HLA testing and final crossmatches are required for presensitized non-renal transplant recipients. We cannot estimate the savings from this reduction.

Revisions for Which There May Be a Negligible Increase in Burden or Costs

- The laboratory must ensure a unidirectional workflow for molecular amplification systems that are not contained in enclosed systems. This includes maintaining physically separate areas for specimen preparation, amplification and product detection and reagent preparation, as applicable. This is a recommended guideline for good laboratory practice by several laboratory professional organizations. Although we are unable to estimate the number of laboratories that perform molecular amplification with open systems without following the recommended guideline, we expect the number to be small and any increase in burden or cost with meeting this new requirement, now at § 493.1101, negligible.

- If the laboratory ceases operation, it must make provisions to ensure that all records, slides, blocks, and tissues are maintained for the applicable time frames. We anticipate that this change now at § 493.1105 will affect few laboratories; however, we cannot estimate the number or associated cost.

- In the former requirements at §§ 493.911(c)(1), 493.913(c)(1), 493.915(c)(1), 493.917(c)(1), 493.919(c)(1), 493.923(b)(1), 493.927(c)(1), 493.931(c)(1), 493.933(c)(1), 493.937(c)(1), and 493.941(c)(1) PT programs were required to grade PT results by first comparing the laboratory's response to the response which reflects agreement of either 90 percent of 10 or more referee laboratories or 90 percent or more of all participating laboratories. If this consensus agreement requirement was met, then the results could be graded based on their values relative to the established correct response for each PT analyte, subspecialty, or specialty. If the consensus requirement was not met, then laboratories were not graded and received an acceptable score, by default.

As a consequence of this, a portion of those laboratories receiving ungraded PT results may have failed to recognize that their actual PT performance was not acceptable and only realized that their performance was unacceptable when their PT results were reviewed as part of an inspection. Thus, in some instances laboratories failed to make appropriate corrections to testing problems, identified by unacceptable PT performance, in a timely manner. Now at §§ 493.911(c)(1), 493.913(c)(1), 493.915(c)(1), 493.917(c)(1), 493.919(c)(1), 493.923(b)(1), 493.927(c)(1), 493.931(c)(1), 493.933(c)(1), 493.937(c)(1), and 493.941(c)(1), the consensus agreement requirement is lowered to 80 percent. Fewer PT results will be ungraded and a portion of those laboratories previously not graded due to a lack of consensus will receive an unacceptable PT grade. Thus, these laboratories will be alerted to potential testing problems sooner. Also, with the change at § 493.1236(b)(2), which now requires all laboratories to verify testing accuracy for any analyte, subspecialty, or specialty assigned a PT score that does not reflect the laboratory's actual PT performance, an additional number of laboratories may become cognizant of their poor testing performance sooner than when PT results are not graded and they receive an acceptable score by default. The combination of fewer ungraded PT results with the requirement for all laboratories to review and verify their PT results, especially when they are deemed questionable by the PT program, will result in these laboratories, in a more timely manner, identifying and correcting potential sources of error which may not have been otherwise detected, thereby increasing overall laboratory accuracy. However, there may be some burden for those laboratories that are now required to verify testing accuracy but are having no real problem with testing. Since verifying testing accuracy whenever there is a potential likelihood of error is generally regarded as good laboratory practice, and in most instances the laboratory's routine use of QC may be used to verify testing accuracy, this should not be considered burdensome. Likewise, PT programs may be slightly inconvenienced by the need to change their grading algorithms to accommodate the 80 percent consensus requirement. However, it is the responsibility of PT programs to assist laboratories in assessing their testing performance by providing PT samples that can be appropriately graded.