

single control, we are unable to accurately estimate the change.

Similarly, in paragraph (a), the laboratory must check each batch, lot number and shipment of lactophenol cotton blue for intended reactivity with control organism(s). Previously, control testing of this stain was required daily. As described above, since the decrease in this burden for documenting a single control result is minor, we are unable to accurately estimate the change.

Section 493.1269 Standard:
Hematology

In the former regulations for the specialty of hematology, under paragraph (b), nonmanual hematology testing systems, excluding coagulation, the laboratory was required to include two levels of control materials each 8 hours of operation. In this final rule, this requirement has been revised from every 8 hours to each day of testing under § 493.1256 and results in decreased reporting.

The revisions to this requirement result in a decrease in documenting control results since the requirement has been revised from every 8 hours to each day of testing.

Previously, we had included these reporting requirements with the general QC procedures. However, since these requirements are now under the condition, Analytic systems, at § 493.1250, we have removed these hematology requirements from the general QC procedures and placed them under Control procedures at § 493.1256.

Former Burden: Hospital and Independent Laboratories

The total number of laboratories performing hematology testing is 32,753. Of this total, 5,329 are hospitals, 3,867 are independent laboratories, 17,844 are physician's office laboratories (POLs), and 5,713 fall into a miscellaneous category of others. We assume that this burden will affect most hospitals and independent laboratories since these laboratories typically operate 24 hours per day for 30 days a month. Therefore, the burden for these laboratories is $5 \text{ min./day} \times 30 \text{ days/month} = 150 \text{ min./month} = 2.5 \text{ hrs./month}$. $2.5 \text{ hrs./month} \times 12 = 30 \text{ hrs./laboratory/yr.}$ $9,196 \text{ hospital and independent laboratories} \times 30 \text{ hrs./yr.} = 275,880 \text{ hrs./yr.}$

Change in Burden: Hospital and Independent Laboratories

Since this final rule will only require controls once a day, we are allowing a $\frac{2}{3}$ decrease in burden for these laboratories. Therefore, the decrease in

burden will be $\frac{2}{3}$ of 275,880 hrs./yr. = 183,920 hrs./yr.

In addition, the new burden for hospital and independent laboratories is 275,880 hrs./yr.—183,920 hrs./yr. = 91,960 hrs./yr.

Former Burden: POLs

For POLs that only perform hematology for 8 hours a day, there is no reduction in burden. However, many POLs have operating hours that range from 9 to 10 hours a day and these laboratories are currently required to run control materials twice a day. In estimating the burden for this category of laboratories, we are including the POLs and the "other" category for a total of 23,557 laboratories. In addition, we estimate that 50 percent (11,779) of these laboratories operate on a 9 or 10-hour day for 20 days a month and must run control materials twice a day. Therefore, the burden is $3.5 \text{ min./day} \times 20 \text{ days/month} = 70 \text{ min./month} = 1.2 \text{ hrs./month} \times 12 \text{ months/yr.} = 14 \text{ hours/laboratory/yr.}$ $\times 11,779 \text{ laboratories (operating on a 9 or 10 hour day)} = 164,906 \text{ hrs./yr.}$

The remaining 50 percent of the POLs that only operate on an 8-hour day have no change in burden that is, $1.75 \text{ min./day} \times 20 \text{ days/month} = 35 \text{ min./month} = 0.6 \text{ hrs./month}$. $0.6 \text{ hrs./month} \times 12 \text{ months/yr.} = 7 \text{ hours/laboratory/yr.}$ $11,779 \text{ laboratories (operating on an 8-hour day)} \times 7 \text{ hours/yr.} = 82,453 \text{ hrs./yr.}$

Change in Burden: POLs

In this final rule, all laboratories will only be required to run control materials once each day. Therefore, the POLs operating on a 9 or 10-hour schedule will have their burden decreased by 50 percent. The estimated decrease in burden for this group of laboratories under this requirement is $11,779 \text{ POLs (operating on 9 or 10 hour day)} \times 7 \text{ hrs./yr.} = 82,453 \text{ hrs./yr.}$

Former Burden: Total

The total estimated burden was 275,880 hrs./yr. (hospital and independent laboratories) + 164,906 hrs./yr. (POLs operating on a 9 or 10 hour day) + 82,453 hrs./yr. (POLs operating on an 8 hour day) = 523,239 hrs./yr.

Change in Burden: Total

The total estimated decrease in burden for this requirement under this final rule is 183,920 hrs./yr. (hospital and independent laboratories) + 82,453 hrs./yr. (POLs) = 266,373 hrs./yr.

Burden in This Final Rule

The total estimated burden under this final rule is 91,960 hrs./yr. (hospital and independent laboratories) + 164,906 hrs./yr. (total POLs, those operating on a 9 or 10 hour day and those operating on an 8 hour day) = 256,866 hrs./yr.

Section 493.1273 Standard:
Histopathology

The revisions to this requirement result in an increase in reporting from one control slide to two control slides for each group of slides for immunohistochemical stains. Previously, we included these reporting requirements with the general QC procedures. The requirements are now under the condition Analytic systems at § 493.1250 as requirements for Histopathology at § 493.1273. Although this is an increase in reporting from one control slide to two, we cannot estimate the laboratory burden because we do not know the number of laboratories that perform immunohistochemical stains or how often the staining is performed. Additionally, many of the laboratories performing immunohistochemical stains were already testing both a positive and negative control material, and some immunohistochemical stains can be checked for a negative reaction on the same slide that contains positive reactive cells. We expect that this revision will only affect a limited number of laboratories, and the increase in burden will be small.

Section 493.1278 Standard:
Histocompatibility

In the former § 493.1265(a)(13), the laboratory was required to have, at least once each month, each individual performing tests evaluate a previously tested specimen as an unknown to verify his or her ability to reproduce test results. Records of the results for each individual had to be maintained. These requirements are deleted in this final rule.

Former Burden

There is a reduction in burden for this specialty since, in this final rule, we are no longer requiring the laboratories to, at least once each month, have each individual performing tests evaluate a previously tested specimen as an unknown to verify his or her ability to reproduce test results. Therefore, we estimate that the former reporting burden for this activity to be 3 min./day for each individual, or $3 \text{ min./day} \times 1 \text{ month} = 3 \text{ min./month} \times 12 \text{ months/yr.} = 36 \text{ min/yr.} = 0.6 \text{ hrs/individual/yr.}$

We estimate an average histocompatibility laboratory to employ three individuals. Therefore, the former