

2003, under the phase-in provision, to continue to qualify as directors of laboratories performing high complexity testing.

- We revised the requirement at § 493.1443(b)(3)(i) by removing the list of HHS-approved boards. We are placing the list in Appendix C of the State Operation Manual (CMS Pub. 7) to allow more timely updates.

- We revised § 493.1445(e)(5) to refer to the quality assessment program.

- We revised § 493.1451(c)(4) by removing the reference to § 493.1257(c) and adding, in its place § 493.1274(d) and (e).

- We revised § 493.1471(b)(2) and § 493.1485(a) by removing “§ 493.1257(d),” and adding, in its place, “§ 493.1274(c).”

#### *Removal of Subpart P*

As stated in section II of this preamble (Highlights and Organization of Final Rule), we incorporated the former “Subpart P—Quality Assurance; Moderate Complexity (Including the Subcategory) or High Complexity Testing, or Any Combination of These Tests” under the appropriate sections now located in Subpart K, General Laboratory Systems, Preanalytic Systems, Analytic Systems, and Postanalytic Systems.

#### *Subpart R—Enforcement Procedures*

- We revised § 493.1844 by removing the reference to “subpart P.”

#### *Subpart T—Consultations*

- We revised § 493.2001(e)(1) to read “Criteria for categorizing nonwaived testing.”

- We revised § 493.2001(e)(4) to read “Facility administration and quality systems standards;”

### **VI. Collection of Information Requirements**

Under the Paperwork Reduction Act (PRA) of 1995, we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the PRA requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.

- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

We are soliciting public comment on each of these issues for the sections that contain new information collection requirements. Except as indicated below, all of the information collection burden in this final rule has been approved by the OMB under approval number 0938–0612 through June 2004.

Because the sections in this final rule are a reorganization of former sections, the burden approval numbers cited state the best approximation we could make for which combinations of former burden numbers match with the sections as specified in this final rule. Our approximations are as follows:

#### Section 493.1105 Standard: Retention Requirements

Under paragraph (a)(6), Test reports, the laboratory must retain or be able to retrieve a copy of the original report (including final, preliminary, and corrected reports) at least 2 years after the date of reporting.

The change in this paragraph is that now the laboratory has the option of either retaining a copy of the report or having the capability of generating a copy of the report. This revision does not change the burden captured under OMB approval number 0938–0612.

#### Section 493.1241 Standard: Test Request

At paragraph (c), the laboratory must ensure that the written or electronic test requisition solicits the following:

- The sex and age or date of birth of the patient.
- The source of the specimen, as appropriate.
- The date and, if appropriate, time of specimen collection.
- Any additional information relevant and necessary to a specific test to ensure accurate and timely testing, and reporting of results, including interpretation, if applicable.

These new requirements mandate that laboratories solicit the sex and age or date of birth of the patient and, if appropriate, the source of the specimen and the time of specimen collection on the test request. In addition, the requirements clarify that the relevant information needed to ensure accurate and timely testing and reporting of results includes relevant information for interpretation of results.

We believe the burden of soliciting this information is minimal, as it is routinely captured by laboratories as part of good business practices. Therefore, while this information

collection requirement is subject to the PRA, we believe the burden is exempt as defined in 5 CFR 1320.3(b)(2) because the time, effort, and financial resources necessary to comply with the requirement are incurred by persons in the normal course of their activities.

#### Section 493.1242 Standard: Specimen Submission, Handling, and Referral

At paragraph (a), we are clarifying the requirement, formerly at § 493.1103(a), that the laboratory’s written policies and procedures for specimen labeling specify that the patient’s name or unique patient identifier, and when appropriate, specimen source be on the specimen label. This revision does not add additional reporting burden for this requirement under OMB approval number 0938–0612.

#### Section 493.1251 Standard: Procedure Manual

Paragraph (b)(13) requires that the procedure manual include the laboratory’s system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting “panic or alert values.”

This requirement, formerly at § 493.1211(b)(14), now includes the provision for a written procedure describing the laboratory’s processes for entering results into patient records. This revision does not change the paperwork burden captured for this requirement under OMB approval number 0938–0612.

#### Section 493.1253 Standard: Establishment and Verification of Performance Specifications

Each laboratory that introduces an unmodified, FDA-cleared or approved test system must, before reporting patient test results, demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the specified performance characteristics.

In addition, each laboratory that uses a test system in which performance specifications are not provided by the manufacturer, modifies an FDA-cleared or approved test system or introduces a test system not subject to FDA clearance or approval (includes standardized methods and methods developed in-house) must, before reporting patient test results, establish for each test system the performance specifications for specified performance characteristics.

Based upon the performance specifications verified or established, the laboratory must determine calibration procedures and control