TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN ¹

<table>
<thead>
<tr>
<th>21 CFR section/activity</th>
<th>Number of respondents</th>
<th>Number of responses per respondent</th>
<th>Total annual responses</th>
<th>Average burden per response</th>
<th>Total hours</th>
</tr>
</thead>
<tbody>
<tr>
<td>610.2, Requests for Samples and Protocols; Official Release</td>
<td>72</td>
<td>82.972</td>
<td>5,974</td>
<td></td>
<td>17,922</td>
</tr>
<tr>
<td>660.6(b), Protocols</td>
<td>3</td>
<td>4</td>
<td>12</td>
<td>5</td>
<td>60</td>
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<td>660.36(a)(2) and (b), Samples and Protocols</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>6</td>
<td>6</td>
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<td>660.46(b), Protocols</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>5</td>
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<tr>
<td>Total</td>
<td>77</td>
<td></td>
<td>5,988</td>
<td></td>
<td>17,993</td>
</tr>
</tbody>
</table>

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

Our estimated burden for the information collection reflects an overall decrease of 1,463 hours and a corresponding decrease of 491 responses. We attribute this adjustment to a decrease in the number of submissions we received over the last few years.


Lauren K. Roth,
Acting Principal Associate Commissioner for Policy.

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BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration


AGENCY: Substance Abuse and Mental Health Services Administration, Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Department of Health and Human Services (HHS) notifies Federal agencies of the laboratories and Instrumented Initial Testing Facilities (IITFs) currently certified to meet the standards of the mandatory guidelines for Federal Workplace Drug Testing Programs using urine and/or oral fluid (Mandatory Guidelines).

The Mandatory Guidelines using urine were first published in the Federal Register on April 11, 1988 (53 FR 11970), and subsequently revised in the Federal Register on June 9, 1994 (59 FR 29908); September 30, 1997 (62 FR 51118); April 13, 2004 (69 FR 16644); November 25, 2008 (73 FR 71858); December 10, 2008 (73 FR 75122); and on January 23, 2017 (82 FR 7920).

The Mandatory Guidelines using oral fluid were first published in the Federal Register on October 25, 2019 (84 FR 57554) with an effective date of January 1, 2020.

In accordance with the Mandatory Guidelines using oral fluid dated October 25, 2019 (84 FR 57554), the following HHS-certified laboratories meet the minimum standards to conduct drug and specimen validity tests on oral fluid specimens: At this time, there are no laboratories certified to conduct drug and specimen validity tests on oral fluid specimens.

HHS-Certified Instrumented Initial Testing Facilities Approved To Conduct Urine Drug Testing

In accordance with the Mandatory Guidelines using urine dated January 23, 2017 (82 FR 7920), the following HHS-certified laboratories allow for oral fluid drug testing have been published. The Mandatory Guidelines require strict standards that laboratories and IITFs must meet in order to conduct drug and specimen validity tests on specimens for federal agencies. HHS does not allow IITFs to conduct oral fluid testing.

To become certified, an applicant laboratory or IITF must undergo three rounds of performance testing plus an on-site inspection. To maintain that certification, a laboratory or IITF must participate in a quarterly performance testing program plus undergo periodic, on-site inspections.

Labs and IITFs in the applicant stage of certification are not to be considered as meeting the minimum requirements described in the HHS Mandatory Guidelines using urine or oral fluid. An HHS-certified laboratory or IITF must have its letter of certification from HHS/SAMHSA (formerly: HHS/NIDA), which attests that the test facility has met minimum standards. HHS does not allow IITFs to conduct oral fluid testing.

HHS-Certified Laboratories Approved To Conduct Oral Fluid Drug Testing

In accordance with the Mandatory Guidelines using oral fluid dated October 25, 2019 (84 FR 57554), the following HHS-certificated laboratories meet the minimum standards to conduct drug and specimen validity tests on oral fluid specimens: At this time, there are no laboratories certified to conduct drug and specimen validity tests on oral fluid specimens.

HHS-Certified Laboratories Approved To Conduct Oral Fluid Drug Testing

In accordance with the Mandatory Guidelines using oral fluid dated October 25, 2019 (84 FR 57554), the following HHS-certificated laboratories meet the minimum standards to conduct drug and specimen validity tests on oral fluid specimens: At this time, there are no laboratories certified to conduct drug and specimen validity tests on oral fluid specimens.

HHS-Certified Laboratories Approved To Conduct Oral Fluid Drug Testing

In accordance with the Mandatory Guidelines using oral fluid dated October 25, 2019 (84 FR 57554), the following HHS-certificated laboratories meet the minimum standards to conduct drug and specimen validity tests on oral fluid specimens: At this time, there are no laboratories certified to conduct drug and specimen validity tests on oral fluid specimens.
Laboratories certified through that SCC voted to end its Laboratory Accreditation Program for Substance Abuse (LAPSA) effective May 12, 1998. Laboratories certified through that program were accredited to conduct forensic urine drug testing as required by U.S. Department of Transportation (DOT) regulations. As of that date, the certification of those accredited Canadian laboratories will continue under DOT authority. The responsibility for conducting quarterly performance testing plus periodic on-site inspections of those LAPSA-accredited laboratories was transferred to the U.S. HHS, with the HHS’ NLCP contractor continuing to have an active role in the performance testing and laboratory inspection processes. Other Canadian laboratories wishing to be considered for the NLCP may apply directly to the NLCP contractor just as U.S. laboratories do.

Upon finding a Canadian laboratory to be qualified, HHS will recommend that DOT certify the laboratory as meeting the minimum standards of the Mandatory Guidelines published in the Federal Register on January 23, 2017 (82 FR 7920). After receiving DOT certification, the laboratory will be included in the monthly list of HHS-certified laboratories and participate in the NLCP certification maintenance program.