This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: Center for Scientific Review, Special Emphasis Panel.

Date: August 22, 2001.

Time: 10 a.m. to 11 a.m.

Agenda: To review and evaluate grant applications.

Place: NIH, Rockledge 2, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Angela M. Pattatucci-Aragon PhD., Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5220, MSC 7852 Bethesda, MD 20892, (301) 435–1175.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: Center for Scientific Review, Special Emphasis Panel.

Date: August 26–28, 2001.

Time: 7 p.m. to 1 p.m.

Agenda: To review and evaluate grant applications.

Place: Marriott Long Island, 3635 Express Drive North, Islandia, NY 11749.

Contact Person: Eugene Vigil, PhD., Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5144, MSC 7840, Bethesda, MD 20892, (301) 435–1025.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, comparative Medicine, 93,306; 93.333. Clinical Research, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 3.846–93.878, 93.892, 93.892, 93.893, Natioinal Institutes of Health, HHS)

Dated: August 14, 2001.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 01–20927 Filed 8–20–01; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Proposed Collection; Comment Request

In compliance with section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 concerning opportunity for public comment on proposed collections of information, the Substance Abuse and Mental Health Services Administration will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the information collection plans, call the SAMHSA Reports Clearance Officer on (301) 443–7978.

Comments are invited on: (a) Whether the proposed collections of information are necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Proposed Project: Voluntary Customer Satisfaction Surveys to Implement Executive Order 12862 in the Substance Abuse and Mental Health Services Administration (SAMHSA)

OMB No. 0930–0197; Extension—Executive order 12862 directs agencies that ''provide significant services directly to the public'' to ''survey customers to determine the kind and quality of services they want and their level of satisfaction with existing services.'' SAMHSA provides significant services directly to the public, including treatment providers and State substance abuse agencies, through a range of mechanisms, including publications, technical assistance and web sites. Many of these services are focused on information dissemination activities. The purpose of this submission is to extend the existing generic approval for such surveys.

The primary use for information gathered is to identify strengths and weaknesses in current service provisions by SAMHSA and to make improvements that are practical and feasible. Several of the customer satisfaction surveys expected to be implemented under this approval will provide data for measurement of program effectiveness under the Government Performance and Results Act (GPRA). Information from these customer surveys will be used to plan and redirect resources and efforts to improve or maintain a high quality of service to health care providers and members of the public. Focus groups may be used to develop the survey questionnaire in some instances.

The estimated annual hour burden is as follows:

Type of data collection	Number of respondents	Responses/respondent	Hours/response	Total hours
Focus group	150	1	2.50	375
Mail/telephone.e-mail survey	10,000	1	.33	3,300
Total	10,150			3,675

Send comments to Nancy Pearce, SAMHSA Reports Clearance Officer, Room 16–105, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857. Written comments should be received within 60 days of this notice.

Dated: August 14, 2001.

Richard Kopanda,

Executive Officer, Substance Abuse and Mental Health Administration.

[FR Doc. 01–21004 Filed 8–20–01; 8:45 am]

BILLING CODE 4162–20–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Mandatory Guidelines for Federal Workplace Drug Testing Programs

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

ACTION: Notice of proposed revisions.

SUMMARY: The Department of Health and Human Services (HHS) is proposing to establish standards for determining the validity of urine specimens collected under the Mandatory Guidelines for Federal Workplace Drug Testing Programs. These proposed standards are intended to ensure that validity testing and reporting procedures are uniformly applied to all Federal agency urine specimens when a validity test is conducted.

DATES: Submit comments on or before October 22, 2001.

ADDRESSES: Written comments should be sent to Robert L. Stephenson II, M.P.H., Director, Division of Workplace Programs, CSAP, 5600 Fishers Lane, Rockwall II, Suite 815, Rockville, Maryland 20857.

FOR FURTHER INFORMATION CONTACT: Walter F. Vogl, Ph.D., Drug Testing Section, Division of Workplace Programs, CSAP, 5600 Fishers Lane, Rockwall II, Suite 815, Rockville, Maryland 20857, tel. (301) 443–6014, fax (301) 443–3031, or email: *wvogl@samhsa.gov*.

SUPPLEMENTARY INFORMATION:

Background

The Mandatory Guidelines for Federal Workplace Drug Testing Programs (Mandatory Guidelines), as revised in the **Federal Register** on June 9, 1994 (59 FR 29908) and on September 30, 1997 (62 FR 51118), establish the scientific and technical guidelines for Federal workplace drug testing programs and establish standards for certification of laboratories engaged in urine drug testing for Federal agencies under authority of Public Law 100–71, 5 U.S.C. 7301 note, and Executive Order No. 12564.

The current version of the Mandatory Guidelines, at section 2.1(c), permits testing to determine the validity of Federal employees' urine specimens. Specimen validity testing refers to testing conducted by a laboratory to identify any attempt to tamper with a specimen. This includes testing to identify adulteration (e.g., putting a substance into a specimen that is designed to mask or destroy the drug or drug metabolite that the specimen may contain or to adversely affect the assay reagent) or substitution (e.g., diluting a urine specimen with a liquid to effectively decrease the concentration of a drug below the cutoff concentration, or replacing a valid urine specimen with a drug-free specimen). It is expected that laboratories conduct such testing in a forensically sound manner as is required for all of the laboratories' testing. *See* section 3.20(c).

During the past few years, the laboratories certified under the National Laboratory Certification Program (NLCP) have reported that the number of adulterated and substituted urine specimens has been increasing. A recent audit conducted of the 66 certified laboratories in the NLCP identified a total of 6,440 adulterated specimens and 2,821 substituted specimens reported to Medical Review Officers (MROs) during the last two years. These numbers refer to specimens tested under the Federal agency workplace drug testing program and the U.S. Department of Transportation (DOT) regulations (49 CFR part 40) that are applicable to DOT Federally regulated programs with a total of approximately 13 million specimens being tested during this time. The results of this audit suggest that adulteration and substitution are growing concerns within the Federal and Federally regulated workplace drug testing program and that every effort must be made to ensure the complete reliability and accuracy of the validity test results reported by the laboratories.

In response to the reports made by NLCP certified laboratories on the increased number of adulterated and substituted specimens, the Substance Abuse and Mental Health Services Administration (SAMHSA), a component of HHS, and DOT began a process, using the SAMHSA Drug Testing Advisory Board (DTAB), to assist them in developing reasonable standards for the testing and reporting of validity test results for urine specimens tested in the Federal and Federally-regulated programs.

An extensive literature review was conducted to assist HHS and DOT in determining the normal ranges for the routine clinical measurements that could be conducted on urine specimens. The literature review was subsequently published in the *Journal of Analytical Toxicology* (J.D. Cook, Y.H. Caplan, C.P. LoDico, and D.M. Bush. The Characterization of Human Urine for Specimen Validity Determination in Workplace Drug Testing: A Review. *J. Anal. Toxicol.* 24: 579–588 (2000)). Standards were developed as to what were forensically sound criteria for classifying urine specimens as substituted. It was determined that a urine specimen meeting the criteria of creatinine less than or equal to 5.0 mg/dL and specific gravity less than or equal to 1.001 or greater than or equal to 1.020 should be considered a substituted specimen. Such a specimen is not consistent with the clinical characteristics associated with normal human urine. It was further determined that urine specimens with pH values less than or equal to 4.5 and greater than or equal to 8.0 are highly suspect for tampering. Moreover, a urine specimen should be considered adulterated if its pH is less than or equal to 3 or greater than or equal to 11.

To provide additional information about substitution, DOT conducted a study designed specifically to focus on the paired measurements of creatinine concentration and specific gravity in urine specimens provided by a group of volunteers. The text of this study is available on the DOT's Office of Drug and Alcohol Policy and Compliance web site (*www.dot.gov/ost/dapc*). All participants agreed to consume at least 80 ounces of fluid spread evenly over six consecutive hours. The protocol asked each participant to consume 40 ounces of fluid within the first three hours of the six-hour test period. This would be immediately followed by the consumption of at least another 40 ounces in the last three hours of the six-hour period. Urine specimens were collected prior to the start of the six-hour period and at the end of each subsequent hour in the test period. Urine specimens were also collected on awakening the morning of the test day and on awakening the morning following the test day (this amounted to a total of nine urine specimens being requested from each participant). Height, weight, age, gender, ethnicity, eating habits, and medications taken regularly and on the day of the collections were also documented. All urine specimens were sent to an HHS-certified laboratory where creatinine and specific gravity were measured using well-established laboratory techniques. The 56 subjects provided a total of 500 urine specimens. Two participants were unable to consume the minimum amount of fluid originally intended. The remainder consumed at least the minimum requested. Twelve participants (5 men and 7 women) consumed over one gallon of fluid by the end of their test periods. Not one of the 500 specimens was identified as substituted using the HHS criteria to report a specimen as substituted. There was no evidence that individuals, regardless of gender, other factors, or intentionally consuming unusually large amounts of fluids, are capable of physiologically producing urine that satisfy the HHS substitution criteria.

The extensive literature review, the recommendation from the DTAB, and the results of the special substitution study conducted by DOT contributed to HHS and DOT issuing documents that established guidance for reporting urine specimens as substituted or adulterated.[1]

It has come to HHS's attention that, despite the previous guidance set forth by the HHS and DOT, some laboratories did not, in the past, follow the guidance. In the published revision to 49 CFR Part 40, ''Procedures for Transportation

[1] HHS issued NLCP Program Document #35 on September 28, 1998, and NLCP Program Document #37 on July 28, 1999. DOT issued a memorandum to MROs on September 28, 1998, and its revised DOT regulation, 49 CFR Part 40, on December 19, 2000.

Workplace Drug and Alcohol Testing Programs'' (65 FR 79462, December 19, 2000), DOT outlines a series of errors in validity testing. Upon further investigation by HHS, it was discovered that some laboratories had engaged in ''truncating'' creatinine results and certain laboratories had reported tests as substituted that did not meet both substitution criteria for creatinine and specific gravity measurements. *See* 65 FR 79481–82. Because DOT has thoroughly outlined the results of this investigation in its newly-issued Part 40, we do not duplicate that discussion here.

In an effort to eliminate the possibility that HHS-certified laboratories will use different validity testing practices, we find it necessary to explicitly delineate required standards for forensically sound validity testing in the Mandatory Guidelines.

In addition, the Department proposes to require specimen validity testing for all Federal employee urine specimens. Federal agency drug-free workplace programs have been established by more than 120 Executive Branch Federal agencies and have a potential impact on 1.7 million Federal employees. The specimen validity testing and drug testing quality assurance provisions of the NLCP apply equally to all of the laboratories that provide forensic urine drug testing for Federal agencies and, by reference in the DOT regulations at 49 CFR Part 40, employers regulated by DOT.

This notice specifically seeks public comments from the Federal agencies and employees covered by Executive Order 12564 and Public Law 100–71 on the proposal to require specimen validity testing as part of their drug testing programs. We seek comment on all aspects of these proposed guidelines, including comments on special budget and related human resource issues to help inform policy development.

As indicated above, under the proposed new section 2.1(a)(4) of the Guidelines, Federal agencies would be required to have validity tests performed on all Federal employee urine specimens.

The proposed new section 2.4(g) of the Guidelines requires laboratories to conduct validity testing on all Federal employee urine specimens and to comply with the provisions of these Guidelines that specify requirements for conducting validity testing. The HHS literature review, the recommendation by the DTAB, and the article published in the *Journal of Analytical Toxicology* provided the basis for the substitution and adulteration criteria set forth in these required standards and demonstrated that the cutoff levels were scientifically sound. Regarding the portion of validity testing that includes testing for adulterants, the proposed revision to section 2.4(g)(1) of the Guidelines provides that laboratories must perform specific validity tests for oxidizing adulterants (section 2.4(g)(1)(iv)). When there is an indication that a specimen may have been adulterated, laboratories must perform additional validity tests for specific adulterants (section 2.4(g)(v)). With regard to cutoff concentrations for adulterants, only nitrite (section 2.4(k)(ii)) has a specified cutoff concentration in a urine specimen beyond which the specimen can be considered to be adulterated. Other currently identified adulterants are foreign substances that may be toxic.

We have found from experience that the adulterant market is volatile and that the popularity of particular adulterants alternately wax and wane. Moreover, as laboratories become aware of certain adulterants, and develop screening procedures for those substances, other adulterants rise in popularity as a way to ''beat the test.'' Therefore, in order to keep the laboratories informed of known adulterants, HHS will include a list of known adulterants in the monthly **Federal Register** notice that lists the laboratories that meet minimum standards to engage in urine drug testing for Federal agencies and employers regulated by DOT.

All provisions of the Guidelines that regulate laboratories and the conduct of workplace drug testing are applicable to specimen validity testing. In addition, the proposed revision of section 2.6 provides for review of validity test results by a Medical Review Officer (MRO).

Explanations of the proposed changes to the Mandatory Guidelines are presented below according to the section of the Guidelines that they affect.

Subpart A—General

In section 1.2, the Secretary proposes to add new definitions associated with specimen validity testing. These include the definitions for ''adulterated specimen,'' ''confirmatory validity test,'' ''dilute specimen,'' ''initial validity test,'' ''invalid result,'' ''non-negative specimen,'' ''oxidizing adulterant,'' and ''substituted specimen.''

Subpart B—Scientific and Technical Requirements

The Secretary proposes to revise paragraph 2.1(a) to require the workplace drug testing programs of all Federal agencies to have specimen validity tests conducted on all Federal employee urine specimens.

The Secretary proposes to revise paragraph 2.1(c) to clarify that other drug tests are not normally permitted on urine specimens.

The Secretary proposes to revise paragraph 2.2(h)(6) to give the donor the right to request that a split (Bottle B) specimen be tested to confirm an adulteration or substitution result that was reported by the primary laboratory on the primary (Bottle A) specimen. This proposed change in the Guidelines ensures that a donor has the same right to challenge the accuracy of an adulteration or substitution result as a drug positive result on a primary (Bottle A) specimen. This is consistent with DOT's 49 CFR Part 40 regulation, which implemented this requirement as of January 18, 2001.

The Secretary proposes to add a new paragraph 2.4(g), entitled ''Validity Testing.'' This paragraph requires a laboratory to conduct validity testing and establishes the criteria that must be used by a laboratory to report a specimen as adulterated, substituted, invalid, or diluted. As stated in the background information, the criteria for adulteration and substitution are based on the scientific evidence that was available at the time the criteria were established and are used by many laboratories to determine whether specimens are adulterated or substituted. The criteria for reporting an invalid result for a specimen are based on obtaining validity or drug test results that are not within ''normal'' ranges or when a specific adulterant cannot be identified. The criteria for reporting a specimen as dilute were established by DOT in the early 1990s based on a review of the normal values for creatinine and specific gravity.

The Secretary is proposing in paragraph 2.4(g)(2) to establish a pH cutoff for reporting a specimen as adulterated and in paragraph 2.4(g)(3) to establish a creatinine cutoff and a specific gravity cutoff for reporting a specimen as substituted. These cutoff levels have been selected to be outside the normal ranges for these indicators as identified in the extensive literature review conducted by the HHS. The creatinine cutoff established in the literature review is less than or equal to 5 mg/dL; the Secretary proposes a creatinine cutoff of less than 5 mg/dL. The specific gravity cutoff established in the literature review is less than or equal to 1.001; the Secretary proposes a specific gravity cutoff of less than 1.002. The pH cutoff established in the literature review is less than or equal to

3; the Secretary proposes a pH cutoff of less than 3. Using the proposed cutoffs, the creatinine and pH cutoffs are mathematically simplified from the cutoffs developed in the literature review to eliminate errors associated with truncating results. Changing the inequality from ''less than or equal to'' to ''less than'' for creatinine, specific gravity, and pH was also done for clarity and consistency with respect to all other drug test cutoffs. These changes are also consistent with the required number of significant digits for creatinine and pH measurements. With regard to specific gravity, using a cutoff of less than 1.002 is essentially the same as using a cutoff of less than or equal to 1.001. Most of the instruments currently used for measuring specific gravity only read differences of 0.001 (i.e., to 3 decimal places). Therefore, specific gravity readings of 1.000 and 1.001 will continue to be considered as substituted specimens when combined with a creatinine less than 5 mg/dL. A specimen with a specific gravity reading of 1.002 and a creatinine less than 5 mg/dL would be reported as invalid.

The Secretary is proposing to revise paragraph 2.4(i), redesignated as paragraph 2.4(j), to require a second laboratory to conduct validity tests when it is unable to reconfirm the drug or drug metabolite that was originally reported positive in a single specimen or primary (Bottle A) specimen. This policy ensures that every effort is made by the second laboratory to determine the reason for not reconfirming the presence of the drug or drug metabolite in a urine specimen. This proposed change is consistent with DOT regulation 49 CFR Part 40.

The Secretary is also proposing to add a new paragraph 2.4(k) and a new paragraph 2.4(l) which outline the criteria for retesting a specimen for adulterants and substitution.

The Secretary proposes to add new paragraphs 2.5 (d) through (j) that will establish specific quality control criteria and other procedural and test requirements for performing each individual validity test.

The Secretary proposes to revise paragraphs 2.6(a), (b), and (c) to clarify the qualifications and responsibilities of the MRO and to expand the MRO's duties to review adulteration, substitution, and invalid test results reported by the laboratory. These proposed changes are consistent with DOT regulation 49 CFR Part 40.

The Secretary proposes to revise paragraph 2.6(e) to ensure that a donor has the same right to challenge the accuracy of a positive, adulterated, or substituted result reported for a single specimen collection as for a split specimen collection. *See* paragraph 2.2(h)(6).

The Secretary proposes to revise paragraph 2.6(g) to ensure that an MRO will notify the designated HHS regulatory office that is responsible for the laboratory certification program when a second laboratory fails to reconfirm a non-negative result reported by a first laboratory. This proposed change is consistent with the notification requirement in DOT regulation 49 CFR Part 40.

Subpart C—Certification of Laboratories Engaged in Urine Drug Testing for Federal Agencies

The Secretary proposes to revise paragraph 3.2(b) to expand the performance testing program and the laboratory inspection program to include, respectively, performance testing samples to challenge the laboratories' ability to correctly perform validity tests and ensure that the validity testing procedures used by the laboratories are inspected and evaluated in a manner similar to that for all other laboratory operations.

Dated: June 28, 2001.

Joseph H. Autry III,

Acting Administrator, SAMHSA.

Dated: July 13, 2001.

Tommy G. Thompson,

Secretary.

The following amendments are proposed to the Mandatory Guidelines for Federal Workplace Drug Testing Programs published on June 9, 1994 (59 FR 29916):

Subpart A

Add the following definitions to Section 1.2:

Adulterated Specimen. A urine specimen containing a substance that is not a normal constituent or containing an endogenous substance at a concentration that is not a normal physiological concentration.

Confirmatory Validity Test. A second test performed on a different aliquot of the original urine specimen to further support a validity test result.

Dilute Specimen. A urine specimen with creatinine and specific gravity values that are lower than expected for human urine.

Initial Validity Test. The first test used to determine if a urine specimen is adulterated, diluted, or substituted.

Invalid Result. Refers to the result reported by a laboratory for a urine specimen that contains an unidentified adulterant, contains an unidentified interfering substance, has an abnormal physical characteristic, or has an endogenous substance at an abnormal concentration that prevents the laboratory from completing testing or obtaining a valid drug test result.

Non-Negative Specimen. A urine specimen that is an adulterated, substituted, positive (for a drug or drug metabolite), or invalid specimen.

Oxidizing Adulterant. A substance that acts alone or in combination to oxidize drugs or drug metabolites that may prevent the detection of a drug, drug metabolite, or effects the reagents in either the initial or confirmatory drug test. Examples of these agents include, but are not limited to, nitrites, pyridinium chlorochromate, chromium(VI)/chromates, bleach, iodine/iodide, halogens, peroxidase, and hydrogen peroxide.

Substituted Specimen. A urine specimen with creatinine and specific gravity values that are so diminished or incongruent that they are not consistent with normal human urine.

Subpart B

1. In section 2.1, revise paragraphs (a)(1), (a)(2), and (a)(3) and insert a new paragraph (a)(4) to read as follows:

(1) Federal agency applicant and random drug testing programs shall, at a minimum, test urine specimens for marijuana and cocaine;

(2) Federal agency applicant and random drug testing programs may also test urine specimens for opiates, amphetamines, and phencyclidine;

(3) When conducting reasonable suspicion, post accident, or unsafe practice testing, a Federal agency may have a urine specimen tested for any drug listed in Schedule I or II of the CSA; and

(4) Federal agency drug testing programs shall have validity tests performed on urine specimens, as provided under section 2.4(g).

2. In section 2.1, revise paragraph (c) to read as follows:

(c) Urine specimens collected pursuant to Executive Order 12564, Public Law 100–71, and these Guidelines shall not be used for any other analysis or test unless authorized by an agency's drug-free workplace program.

3. In section 2.2, revise paragraph (h)(6) to read as follows:

(6) If the test of the primary (Bottle A) specimen is verified positive, adulterated, or substituted by the MRO, the MRO shall report the result to the agency. Only the donor may request through the MRO that the split (Bottle B) specimen be tested by a second certified laboratory to reconfirm the positive, adulterated, or substituted

result reported by the primary laboratory. The MRO shall honor the request if it is made within 72 hours after informing the donor that a positive, adulterated, or substituted result was being reported to the agency. The second laboratory shall test the split specimen in accordance with the requirements in section 2.4 pertaining to retesting for drugs, adulterants, or substitution.

4. In section 2.4, add a new paragraph (g) to read as follows:

(g) *Validity Testing.* (1) A certified laboratory:

(i) Shall determine the creatinine concentration on every specimen;

(ii) Shall determine the specific gravity on every specimen for which the creatinine concentration is less than 20 mg/dL;

(iii) Shall determine the pH on every specimen;

(iv) Shall perform validity test(s) for substances that are commonly known as oxidizing adulterants; and

(v) Shall perform additional validity tests when the following conditions are observed:

(A) Abnormal physical characteristics (e.g., color, odor, excessive foaming);

(B) Reactions or responses characteristic of an adulterant obtained during initial or confirmatory drug tests (e.g., non-recovery of standards, unusual response); or

(C) Possible unidentified interfering substance or adulterant.

The choice of additional validity tests is dependent on the observed indicators or characteristics as described in (v)(A) to (C).

(2) A urine specimen from a single specimen collection or the primary (Bottle A) specimen from a split specimen collection is reported adulterated when:

(i) The nitrite concentration is confirmed to be greater than or equal to 500 mcg/mL;

(ii) The pH is less than 3 or greater than or equal to 11;

(iii) The specimen contains an exogenous substance (i.e., a substance which is not a normal constituent of urine); or

(iv) The specimen contains an endogenous substance at a concentration greater than what is considered a normal physiological concentration.

(3) A urine specimen from a single specimen collection or the primary (Bottle A) specimen from a split specimen collection is reported substituted when both the initial and confirmatory creatinine tests and initial and confirmatory specific gravity tests have the following results:

(i) The creatinine concentration is less than 5 mg/dL; and

(ii) The specific gravity is less than 1.002 or greater than or equal to 1.020.

(4) A urine specimen from a single specimen collection or the primary (Bottle A) specimen from a split specimen collection is reported dilute when the initial or confirmatory tests have creatinine and specific gravity results of:

(i) The creatinine concentration is less than 20 mg/dL;

(ii) The specific gravity is less than 1.003; and

(iii) The creatinine and specific gravity results do not meet the criteria for a substituted or invalid result.

(5) A urine specimen from a single specimen collection or the primary (Bottle A) specimen from a split specimen collection is reported as an invalid result when:

(i) The laboratory detects an adulterant or interferent that it is unable to identify and the analysis has been performed on at least two separate aliquots of specimen;

(ii) The laboratory performs only one colorimetric surfactant test on at least two separate aliquots of the specimen;

(iii) The laboratory documents an interference with the GC/MS drug confirmation assay on at least two separate aliquots of the specimen;

(iv) The laboratory documents incongruent creatinine and specific gravity results (e.g., a creatinine less than 5 mg/dL on both the initial and confirmatory tests and a specific gravity greater than or equal to 1.002 and less than 1.020 on either the initial or confirmatory tests, the laboratory documents a specific gravity of 1.000 on both the initial and confirmatory tests and a creatinine greater than or equal to 5 mg/dL on either the initial or confirmatory tests, or a creatinine greater than or equal to 5 mg/dL and less than 20 mg/dL on either the initial and confirmatory tests and a specific gravity greater than or equal to 1.020 on both the initial and confirmatory tests); or

(v) The laboratory documents a pH less than 4 or greater than or equal to 10 on at least two separate aliquots of specimen and does not meet the criteria for an adulterated specimen.

5. In section 2.4, redesignate paragraphs (g) and (h) as (h) and (i).

6. In section 2.4, paragraph (i) is redesignated as (j) and revised to read as follows:

(j) *Retesting a Specimen for Drugs.* (1) A second laboratory shall use the laboratory's confirmatory drug test when retesting an aliquot of a single specimen or testing a split (Bottle B) specimen for the drug or drug metabolite that was reported positive in the single specimen or the primary (Bottle A) specimen by the first laboratory.

(2) Because some drugs or drug metabolites deteriorate during storage, the retest of an aliquot of a single specimen or the test of a split (Bottle B) specimen is not subject to a specific drug cutoff requirement, but must provide data sufficient to confirm the presence of the drug or metabolite.

(3) If the second laboratory fails to reconfirm the presence of the drug or drug metabolite that was reported by the first laboratory, the second laboratory shall conduct validity tests in an attempt to determine the reason for being unable to reconfirm the presence of the drug or drug metabolite. The second laboratory should conduct the same validity tests as it would conduct on a single specimen or a primary (Bottle A) specimen and reports those results to the MRO. If the second laboratory fails to determine that the aliquot of the single specimen or the split (Bottle B) specimen is adulterated or substituted, the MRO may request the second laboratory to transmit the aliquot or split (Bottle B) specimen to another HHS-certified laboratory for further testing.

7. In section 2.4, a new paragraph (k) is added to read as follows:

(k) *Retesting a Specimen for Adulterants.* (1) A second laboratory shall use one of the following criteria to reconfirm an adulterated result when retesting an aliquot of a single specimen or testing a split (Bottle B) specimen:

(i) pH shall be measured using the laboratory's confirmatory pH test with the appropriate cutoff (i.e., either less than 3 or greater than or equal to 11);

(ii) Nitrite shall be measured using the laboratory's confirmatory nitrite test with a cutoff concentration of greater than or equal to 500 mcg/mL; or

(iii) For adulterants without a specified cutoff (e.g., glutaraldehyde, surfactant, chromate, pyridine, halogens (such as, bleach, iodine), peroxidase, peroxide, other oxidizing agents), the laboratory shall use its confirmatory validity test at an established limit of detection (LOD)/limit of quantitation (LOQ) to reconfirm the presence of the adulterant.

(2) The second laboratory may only conduct the confirmatory validity test(s) needed to reconfirm the adulterant result reported by the primary laboratory.

8. In section 2.4, add a new paragraph (l) to read as follows:

(l) *Retesting a Specimen for Substitution.* (1) A second laboratory

shall use the following criteria to reconfirm a substituted result when retesting an aliquot of a single specimen or testing a split (Bottle B) specimen:

(i) The creatinine shall be measured using the laboratory's confirmatory creatinine test with a cutoff concentration of less than 5 mg/dL; and

(ii) The specific gravity shall be measured using the laboratory's confirmatory specific gravity test with the specified cutoffs of less than 1.002 or greater than or equal to 1.020.

(2) The second laboratory may only conduct the confirmatory validity test(s) needed to reconfirm the validity test result(s) reported by the primary laboratory.

9. In section 2.4, redesignate paragraphs (j) through (n) as (m) through (q).

10. In section 2.5, add a new paragraph (d) to read as follows:

(d) *Laboratory Quality Control Requirements for Validity Tests.* (1) A validity test result for a specimen shall be based on performing an initial (first) validity test on one aliquot and a confirmatory (second) validity test on a second aliquot. In some cases, both validity tests may use the same procedure, instrument, and/or method.

(2) The performance characteristics (e.g., accuracy, precision, LOD, LOQ, linearity, specificity) shall be documented for each validity test as appropriate.

(3) The LOD shall be determined for those adulterants that do not have a cutoff otherwise specified in these Guidelines (e.g., glutaraldehyde, halogens, chromates).

(4) Each analytical run of specimens for which an initial or confirmatory validity test is being performed shall include the appropriate calibrators and controls.

11. In section 2.5, add a new paragraph (e) to read as follows:

(e) *Specific requirements for measuring creatinine concentration.* (1) The creatinine concentration shall be measured to one decimal place on both the initial test and the confirmatory test.

(2) The initial creatinine test shall have a calibrator at either 5 mg/dL or at 20 mg/dL.

(3) The initial creatinine test shall have a control in the range of 2 mg/dL to 4 mg/dL, a control in the range of 5 mg/dL to 20 mg/dL, and a control in the range of 21 mg/dL to 25 mg/dL.

(4) The confirmatory creatinine test (performed on those specimens with a creatinine concentration less than 5 mg/dL on the initial test) shall have a calibrator at 5 mg/dL or at 20 mg/dL, a control in the range of 2 mg/dL to 4 mg/dL, and a control in the range of 6 mg/dL to 8 mg/dL.

12. In section 2.5, add a new paragraph (f) to read as follows:

(f) *Specific requirements for measuring specific gravity.* (1) The specific gravity shall be measured using a refractometer on both the initial and confirmatory specific gravity tests in order to report a specimen as substituted. Dilute specimens may, however, be reported based on refractometer results from the initial test. The refractometer shall be capable of reading in increments of at least 0.001 or less.

(2) The initial and confirmatory specific gravity tests shall have a calibrator at 1.000.

(3) The initial and confirmatory specific gravity tests shall have the following controls:

(i) For the cutoff of less than 1.002, one control at 1.001 and one control in the range of 1.002 to 1.010.

(ii) For the cutoff of greater than or equal to 1.020, one control greater than or equal to 1.020 but not greater than 1.025, and one control in the range of 1.015 to 1.020.

13. In section 2.5, add a new paragraph (g) to read as follows:

(g) *Specific requirements for measuring pH.* (1) Dipsticks, pH paper, and spectrophotometric/colorimetric tests that have a narrow dynamic range and lack the accuracy necessary to support the specified program cutoffs may be used only to determine if the initial and confirmatory pH validity tests must be performed.

(2) Spectrophotometric/colorimetric tests which have the dynamic range and accuracy necessary to support the specified program cutoffs and which are capable of measuring pH to one decimal place may be used as an initial test.

(3) A pH meter capable of measuring the pH to at least one decimal place may be used to perform the initial test and shall be used to perform the confirmatory test.

(4) The initial and confirmatory pH meter tests shall have the following controls:

(i) For the cutoff of less than 3, one control in the range of 2 to 2.9 and one control in the range of 3.1 to 4.

(ii) For the cutoff of greater than or equal to 11, one control in the range of 10 to 10.9 and one control in the range of 11.1 to 12.

(5) Spectrophotometric/colorimetric initial pH tests shall have the following controls:

(i) For the cutoff of less than 3, one control in the range of 2 to 2.9.

(ii) For the cutoff of greater than or equal to 11, one control in the range of 11.1 to 12.

14. In Section 2.5, add a new paragraph (h) to read as follows:

(h) *Specific requirements for performing oxidizing adulterant tests.* (1) At a minimum, the initial test(s) for oxidizing adulterants shall be capable of detecting nitrites, chromates, and halogens (e.g., bleach, iodine). The detection of these adulterants may be achieved by using either a general oxidizing adulterant test or by using specific tests for each category of these adulterants. If an initial test for oxidizing adulterants simultaneously tests for all oxidizing adulterants, the assay shall be able to detect at least the activity equivalent to 20 mcg/mL of chromate (chromium VI) or 200 mcg/mL of nitrite as an LOD. Each analytical run of specimens shall include a control without the compound of interest (i.e., a certified negative control) and at least one positive control with one of the compounds of interest at a concentration which exhibits an oxidizing activity above the documented LOD of the procedure.

(2) A confirmatory test for a specific oxidizing adulterant shall use a different analytical principle or chemical reaction than that used for the initial test unless a recognized reference method is used for both the initial and confirmatory tests. Each analytical run of specimens shall include a control without the compound of interest (i.e., a certified negative control) and a positive control with the compound of interest at a concentration above the documented LOD of the procedure.

15. In section 2.5, add a new paragraph (i) to read as follows:

(i) *Specific requirements for measuring the nitrite concentration.* (1) Dipsticks may only be used to determine if initial and confirmatory nitrite tests shall be performed.

(2) A nitrite specific initial test shall have a calibrator at the cutoff concentration, a negative control (i.e., certified negative urine), one control in the range of 200 mcg/mL to 500 mcg/mL, and one control in the range of 500 mcg/mL to 625 mcg/mL

(3) The confirmatory nitrite test shall have a calibrator at the cutoff concentration, a negative control (i.e., certified negative urine), one control in the range of 200 mcg/mL to 500 mcg/mL, and one control in the range of 500 mcg/mL to 625 mcg/mL.

16. In section 2.5, add a new paragraph (j) to read as follows:

(j) *Specific requirements for performing other validity tests (e.g., glutaraldehyde, surfactants).* (1) Each analytical run of specimens shall include a control without the compound of interest (i.e., a certified negative

control) and a positive control with the compound of interest at a concentration above the documented LOD of the procedure.

(2) A confirmatory test for a specific adulterant shall use a different analytical principle or chemical reaction than that used for the initial test unless a recognized reference method is used for both the initial and confirmatory tests.

(3) The initial and confirmatory tests for anionic surfactants shall be able to detect at least the activity equivalent to 100 mcg/mL of dodecylbenzene sulfonate.

17. In section 2.5, redesignate paragraph (d) as paragraph (k).

18. In section 2.6, rename and revise paragraph (a) to read as follows:

(a) *Medical Review Officer Qualifications.* (1) An MRO shall be a licensed physician (Doctor of Medicine or Osteopathy).

(2) An MRO shall be knowledgeable about and have clinical experience in controlled substance abuse disorders, detailed knowledge of alternative medical explanations for laboratory positive drug test results, and knowledge about issues relating to adulterated and substituted specimens as well as the possible medical causes of specimens having an invalid result.

(3) An MRO may be an employee of the agency or a contractor for the agency; however, an MRO shall not be an employee or agent of or have any financial interest in the laboratory for which the MRO is reviewing drug testing results. Additionally, an MRO shall not derive any financial benefit by having an agency use a specific drug testing laboratory or have any agreement with the laboratory that may be construed as a potential conflict of interest.

19. In section 2.6, rename and revise paragraph (b) to read as follows:

(b) *Medical Review Officer Review of Results.* An essential part of the drug testing program is the final review of each test result reported by a laboratory. A positive drug test result does not automatically identify a donor as an illegal drug user nor does an adulterated, substituted, or invalid test result automatically indicate that a donor has tampered with a specimen. The review of a non-negative test result shall be performed by the MRO before the result is transmitted to the agency's designated representative. Staff under the direct, personal supervision of the MRO may review and report a negative test result to the agency's designated representative. The MRO shall cancel the result for any agency's urine specimen that is not collected or tested in accordance with these Guidelines.

20. In section 2.6, rename and revise paragraph (c) to read as follows:

(c) *MRO Review of Positive, Adulterated, Substituted, or Invalid Test Results.* (1) Prior to making a final decision on a specimen that was reported positive, adulterated, substituted, or an invalid test result by the laboratory, the MRO shall give the donor an opportunity to explain the test result. In carrying out this responsibility, an MRO shall evaluate alternative medical explanations for the positive, adulterated, substituted, or invalid test result. This action should include conducting an interview with the donor, review of the donor's medical history, or review of any other biomedical factors. The MRO shall review medical records made available by the donor when a result could have resulted from taking legally prescribed medication. Following verification of the laboratory test result, the MRO reports the verified result to the agency's designated representative.

(2) When a laboratory reports an invalid result due to the possible presence of an unidentified interfering substance/adulterant, the MRO:

(i) May direct the laboratory to send the specimen to another HHS certified laboratory to possibly identify the interfering substance/adulterant;

(ii) Shall report the result as ''Test Cancelled'' and an immediate direct observed collection is not required if the explanation provided by the donor is acceptable; or

(iii) Shall report the result as ''Test Cancelled'' and indicates that an immediate direct observed collection is required if the explanation provided by the donor is not acceptable.

21. In section 2.6, rename and revise paragraph (e) to read as follows:

(e) *Donor Request to MRO for Retest.* (1) For a positive, adulterated, or substituted result reported on a single specimen or a primary (Bottle A) specimen, a donor may request through the MRO that an aliquot from the single specimen or the split (Bottle B) specimen be tested by a second HHS-certified laboratory to verify the result reported by the first laboratory.

(2) The donor has 72 hours (from the time the MRO notified the donor that his or her specimen was reported positive, adulterated, or substituted) to request a retest of an aliquot from the single specimen or to test the split (Bottle B) specimen.

22. In section 2.6, rename and revise paragraph (g) to read as follows:

(g) *Laboratory Result Not Reconfirmed by a Second Laboratory.* If an MRO finds that a laboratory has reported a test result (i.e., positive, adulterated, or substituted) that a second laboratory is not able to reconfirm in an aliquot from a single specimen collection or in the test of a split (Bottle B) specimen, the MRO shall report the specimen test results to the designated HHS regulatory office.

Subpart C

In section 3.2, revise paragraph (b) to read as follows:

(b) *Need to Set Standards; Inspections.* The ability to accurately determine the presence or absence of specific drugs/metabolites or to accurately determine the validity of a urine specimen is critical to achieving the goals of the testing program and to protect the rights of the Federal employees being tested. Standards have been set which laboratories engaged in Federal employee urine drug testing shall meet to achieve the required accuracy of test results. These laboratories will be evaluated by the Secretary or the Secretary's designee as defined in section 1.2 in accordance with these Guidelines. Applicant laboratories shall test three cycles of performance testing samples that challenge the laboratory's ability to correctly test for drugs and to correctly perform specimen validity tests. Applicant laboratories shall undergo an initial inspection and upon certification are also required to undergo a second inspection within 3 months after being certified. Certified laboratories are required to analyze quarterly performance testing samples that challenge the laboratories to correctly test for drugs and to correctly perform validity tests and to undergo periodic inspections.

[FR Doc. 01–20945 Filed 8–20–01; 8:45 am]

BILLING CODE 4162–20–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

Information Collection Renewal and Revision To Be Submitted to the Office of Management and Budget (OMB) for Approval Under the Paperwork Reduction Act

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Information collection; request for comments.

SUMMARY: The collection of information described below has been submitted to OMB for approval under the provisions of the Paperwork Reduction Act of 1995.