this material from Ms. Colleen Guay-Broder, Office of Science Policy and Public Liaison, NIBIB, NIH, 31 Center Drive MSC 2281, Room 1C14, Bethesda, MD 20892–2281.

The NIBIB looks forward to working with the research community and the public to develop its strategic plan.

Dated: January 14, 2005.

Colleen Guay-Broder,

Director, Office of Science Policy and Public Liaison, National Institute of Biomedical Imaging and Bioengineering, National Institutes of Health.

[FR Doc. 05–1278 Filed 1–24–05; 8:45 am]

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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: Mandatory Guidelines: Response to Public Comments.

SUMMARY: In the **Federal Register** notice of April 13, 2004 (69 FR 19644), the Department of Health and Human Services (''HHS'' or ''Department'') published final changes to the Mandatory Guidelines for Federal Workplace Drug Testing Programs. These changes established specimen validity testing standards and reporting procedures for Federal agency urine specimens collected under the Mandatory Guidelines for Federal Workplace Drug Testing Programs. These changes to the Mandatory Guidelines were subject to further comment only on the creatinine criterion that is part of the requirement to report a urine specimen as substituted because the Department based this criterion on information received after the comment period on the proposed changes published on August 21,2001 closed. After reviewing the comments received regarding this issue, the Department has concluded that the 2 mg/dL creatinine criterion established in the April 13, 2004, **Federal Register** notice (69 FR 19644) for a substituted specimen is the appropriate cutoff concentration to use for reporting a urine specimen as substituted.

EFFECTIVE DATE: November 1, 2004.

FOR FURTHER INFORMATION CONTACT: Walter F. Vogl, Ph.D., Division of Workplace Programs, SAMHSA, Room #2–1035, 1 Choke Cherry Road, Rockville, Maryland 20857, telephone (240) 276–2600, fax (240) 276–2610, or e-mail: *walter.vogl@samhsa.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

The Mandatory Guidelines for Federal Workplace Drug Testing Programs(Mandatory Guidelines) establish the scientific and technical guidelines for Federal workplace drug testing programs and standards for certification of laboratories engaged in urine drug testing for Federal agencies, under authority of section 503 of Pub. L. 100–71, 5 U.S.C. 7301 note, and E. 0. No. 12564. The Mandatory Guidelines were first published in the **Federal Register** on April 11, 1988 (53 FR 11979), revised on June 9, 1994 (59 FR 29908), revised on November 13, 1998 (63 FR 63483), and revised on April 13, 2004 (69 FR 19644).

The April 13, 2004, **Federal Register** notice finalized the changes to the Mandatory Guidelines that were proposed in the **Federal Register** notice published on August 21, 2001 (66 FR 43876); established an effective date of November 1, 2004; but allowed further public comment on one issue. That is, comments were requested on the 2 mg/dL creatinine concentration criterion that was established as part of the requirement to report a urine specimen as substituted. This was left open for comment because the 2 mg/dL concentration level was based on information received after the comment period closed on the **Federal Register** notice published on August 21, 2001. The additional information that was provided indicated that it was possible for an individual to provide a normal urine specimen with a creatinine concentration less than the 5 mg/dL cutoff concentration criterion proposed in the August 21 notice.

II. Discussion of Public Comments

As stated in the April 13, 2004, **Federal Register** notice, the Department was only accepting comments on the creatinine criterion. The Department did receive several comments on other sections of the Mandatory Guidelines including the effective date, but these sections and the effective date were not open to comment.

Several commenters recommended that the Department take one or more of the following actions with regard to the creatinine criterion:

Comment: Immediately collect another specimen from the donor when the creatinine concentration is between 2 mg/dL and 5 mg/dL because this policy will continue to detect ''truly substituted'' specimens.

Response: The suggestion that a urine specimen with a creatinine concentration between 2 mg/dL and 5 mg/dL is ''truly substituted'' implies that the cutoff concentration should be raised to 5 mg/dL to ensure that all substituted specimens are correctly identified as substituted specimens. The Department disagrees with this suggestion. At the Department of Transportation Federal Aviation Administration's conference held February 4–6, 2003, to study substitution and adulteration issues, the experts attending the conference were convinced based on evidence presented that it was possible for some individuals to produce a valid urine specimen with a creatinine concentration of less than 5 mg/dL, the level specified in the **Federal Register** notice of August 21, 2001. After consideration of data on creatinine levels, they concluded that the level should be set at 2 mg/dL. Lowering the concentration level will prevent the likelihood of individuals being falsely accused of substituting their specimen. The Department also notes that there is a second criterion for determining whether a specimen has been substituted—specific gravity—which has not been changed.

Comment: Immediately collect another specimen from the donor when the creatinine concentration is between 2 mg/dL and 5 mg/dL because approximately one half of the second specimens collected from donors in this creatinine range are tested and reported drug positive.

Response: The commenter who submitted this comment did not provide actual data to justify the claim that approximately one-half of the second specimens collected are tested and reported drug positive. The commenter based the observation on specimens between 2 mg/dL and 5 mg/dL that one Medical Review Officer ordered to have a second specimen collected. There was no indication of the number of specimens that were recollected, the reason for testing (*i.e.*, random, post-accident, pre-employment), or whether they were Federal agency, DOT regulated, or private-sector specimens. The commenter did say that all of the recollections that were drug positive were from males and none from females. The Department believes this anecdotal information is not sufficient justification to require immediately collecting a second specimen from a Federal employee or applicant for a Federal agency testing designated position using a direct observed collection. The Department also believes that a urine specimen that tests negative for drugs, is dilute, and exhibits no other evidence of

possible tampering is a valid urine specimen and should not lead a Medical Review Officer to direct a Federal agency to immediately collect another specimen because the creatinine concentration is between 2 mg/dL and 5 mg/dL.

Comment: The creatinine cutoff of less than 2 mg/dL is too low especially when using reagent strips to measure the creatinine concentration.

Response: The Department agrees that reagent strips could not be used to obtain an accurate creatinine concentration at 2 mg/dL. However, since the Department does not permit certified laboratories to use reagent strips to determine creatinine concentration, this comment is not relevant to the creatinine analyses conducted by certified laboratories. The accepted methods to determine creatinine concentration are Jaffe or modified Jaffe colorimetric procedures using autoanalyzers and these methods can accurately analyze and record creatinine concentrations to one decimal place (using mg/dL units) at and below the 2 mg/dL cutoff concentration.

Comment: Donors whose specimens are reported substituted should be directed to provide another specimen using a direct observed collection procedure to prove his or her innocence because the donor naturally produces ''ultra-dilute'' urine.

Response: The Department disagrees with this comment for the following reasons: (1) The revised Mandatory Guidelines give a Federal employee the opportunity to provide medical records to the Medical Review Officer that support a legitimate explanation for a substituted result, and (2) the Federal employee is allowed to request a retest of a single specimen or the test of a split specimen to verify the result reported by the laboratory. The Department believes these two provisions are sufficient to protect the Federal employee's rights without the need to collect a second specimen using a direct observed collection procedure.

Comment: The variation of the measurement of creatinine concentration within and between laboratories is too large to permit determining an accurate measurement of the creatinine concentration.

Response: The Department disagrees with the comment because the results from the performance testing (PT) program clearly demonstrate the ability of the certified laboratories to accurately measure the creatinine concentration around the 2 mg/dL cutoff concentration. With regard to specimen validity tests, certified laboratories are required to ensure that their tests satisfy the strict quality control requirements specified in the Mandatory Guidelines and must implement quality assurance procedures to monitor assay performance. These requirements are essentially the same requirements that have been used and applied to the drug tests since the beginning of the Federal Workplace Drug Testing Program. In addition, the Department monitors the variation of the specimen validity test results through the laboratory inspection and PT programs. The Department believes that monitoring the performance of each laboratory's results on the PT samples that challenge each laboratory's specimen validity tests is sufficient and appropriate to ensure that each laboratory's specimen validity test results on Federal employee specimens are forensically and scientifically supportable; therefore, the Department is not changing the creatinine cutoff concentration.

Comment: Lower the creatinine criterion because certain donors can naturally produce urine specimens with creatinine concentrations that are less than 2 mg/dL.

Response: The Department agrees that under extreme circumstances there may be a few individuals that could theoretically provide a valid urine specimen having a creatinine concentration slightly below 2 mg/dL. However, the Department believes that the policy giving a Federal employee the right to submit medical information to the Medical Review Officer to support a creatinine concentration that is less than 2 mg/dL is a safeguard that will prevent a Federal employee from being falsely accused of providing a substituted specimen.

Dated: December 8, 2004.

Charles G. Curie,

Administrator, SAMHSA.

Dated: January 14, 2005.

Tommy G. Thompson,

Secretary.

[FR Doc. 05–1309 Filed 1–24–05; 8:45 am]

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DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–4971–N–01]

Notice of Submission of Proposed Information Collection to OMB; Requirement for Contractors To Provide Certificates of Insurance for Capital Program Projects

AGENCY: Office of the Chief Information Officer, HUD.

ACTION: Notice.

SUMMARY: The proposed information collection requirement described below has been submitted to the Office of Management and Budget (OMB) for review, as required by the Paperwork Reduction Act. The Department is soliciting public comments on the subject proposal.

HUD is requesting renewed approval to require Public Housing Agencies to obtain certificates of insurance from contractors and subcontractors before beginning work under either the development of a new low-income public housing project or the modernization of an existing project.

DATES: Comments Due Date: February 24, 2005.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB approval Number (2577–0046) and should be sent to: HUD Desk Officer, Office of Management and Budget, New Executive Office Building, Washington, DC 20503; fax: 202–395–6974.

FOR FURTHER INFORMATION CONTACT: Wayne Eddins, Reports Management Officer, AYO, Department of Housing and Urban Development, 451 Seventh Street, SW., Washington, DC 20410; e-mail *Wayne_Eddins@HUD.gov;* or Lillian Deitzer at *Lillian_L_Deitzer@HUD.gov* or telephone (202) 708–2374. This is not a toll-free number. Copies of available documents submitted to OMB may be obtained from Mr. Eddins or Ms. Deitzer and at HUD's Web site at *http://www5.hud.gov:63001/po/i/icbts/collectionsearch.cfm.*

SUPPLEMENTARY INFORMATION: This notice informs the public that the Department of Housing and Urban Development has submitted to OMB a request for approval of the information collection described below. This notice is soliciting comments from members of the public and affecting agencies concerning the proposed collection of information to: (1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information; (3) enhance the quality, utility, and clarity of the information to be collected; and (4) minimize the burden of the collection of information on those who are to respond; including through the use of appropriate automated collection techniques or