

CFR reference	Data collection	No. of respondents	Responses per respondent	Avg burden per response (in hrs.)
73.7(b)	Registration Application	575	1	3.75
73.7(b)	BSL4 Supplement	4	1	2
73.7(e)	Amendment to Registration Application	575	2	1
73.17(a)(e)	Notification Form	10	1	1
73.6(c-e)	Request for Exemption	17	1	1.16
73.14	Transfer of Select Agent	575	5	1.75
73.6(a)(2)	Clinical and Diagnostic Laboratory Exemption Report	1,000	4	1
73.7(i)	Notification of Inactivation	6	1	30/60
73.8(g)	Request Expedited Review	6	1	30/60
73.10(b)	Documentation of Self-inspection	575	1	1
73.13(f)	Documentation of Training	575	1	2
73.18	Administrative Review	14	1	4
73.15(d)	Ensure Secure Record keeping System	575	1	30/60

Dated: August 25, 2003.

Nancy Cheal,

Acting Associate Director for Policy, Planning and Evaluation, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day-68-03]

Proposed Data Collections Submitted for Public Comment and Recommendations

The Centers for Disease Control and Prevention (CDC) publishes a list of information collection requests under review by the Office of Management and Budget (OMB) in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these requests, call the CDC Reports Clearance Officer at (404) 498-1210. Send written comments to CDC, Desk Officer, Human Resources and Housing Branch, New Executive Office Building, Room 10235, Washington, DC 20503 or by fax to (202) 395-6974. Written comments should be received within 30 days of this notice.

Proposed Project

Menthol Crossover Study—New— National Center for Environmental Health (NCEH), Centers for Disease Control and Prevention (CDC). CDC proposes a study to measure differences in African-American and Caucasian smokers in the dose and metabolism of chemicals in smoke from menthol and non-menthol cigarettes.

African-American smokers are more likely than Caucasian smokers to develop some forms of cancer and to have shorter long-term survival after diagnosis. More than 65% of African American smokers smoke menthol cigarettes, compared with about 23% of white smokers. Smoking menthol cigarettes has been associated with higher blood-cotinine levels. Cotinine is a product of the metabolism of nicotine, and the higher cotinine levels suggest that menthol may enable a smoker to obtain more nicotine from each cigarette. In addition, people who smoke menthol cigarettes also have higher levels of carbon monoxide in their breath than do people who smoke non-menthol cigarettes, and an elevated carbon monoxide level is a risk factor for cardiovascular disease. Additionally, the presence of menthol in cigarettes may change the way people smoke cigarettes.

All previous studies have compared people who smoke menthol cigarettes

with those who smoke non-menthol cigarettes; and it is not known whether increased cotinine and carbon monoxide levels in people who smoke menthol cigarettes are attributable to racial or ethnic differences, or a combination of multiple factors. In addition, no previous study has examined the differences between urinary levels of cancer-causing chemicals in people who smoke menthol or non-menthol cigarettes and correlated these findings with smoke exposure intake estimates using salivary cotinine and filter solanesol.

For this two-part crossover study, we will recruit African-American and Caucasian smokers of both sexes who smoke either menthol or non-menthol cigarettes as study subjects. We will determine smoking history then randomly assign each participant to smoking either menthol or non-menthol cigarettes for an initial 2-week period. Study participants then will switch to the opposite type of cigarette for the next 2 weeks. At baseline, and after each 2-week period, we will measure the way the participants smoke the test cigarettes to determine smoking topography. Saliva, urine, and breath samples will be collected to measure by-products of smoking, and participants will complete a brief smoking-history questionnaire. There is no cost to respondents.

Forms	No. of respondents	No. of responses/respondent	Average burden/response (in hours)	Total burden in hours
Response to Flyer: Screening Interview Form	200	1	5/60	17
Site Visits: Check in, Study Information, Visit 1, 2, 3	71	3	15/60	53
Consent Form, Questionnaire, Visit 1, 2, 3	71	3	15/60	53
Urine Sample and Saliva Sample, Visit 1, 2, 3	71	3	15/60	53
Breath Carbon monoxide (CO) Sample: Test Smoke 1, Breath CO Sample; Test Smoke 2, Breath CO Sample; Visit 1, 2, 3	71	3	45/60	160
Sample Test Cigarettes, Distribute Baggies & Cigarettes, Visit 1 and 2	71	2	15/60	36
Instructions and Check out, Visit 1 and 2	71	2	15/60	36
Smoking Cessation Advice, Visit 3 only	71	1	15/60	18

Forms	No. of respondents	No. of responses/respondent	Average burden/response (in hours)	Total burden in hours
Final Check Out, Visit 3 only	71	1	15	18
Total	444

Dated: August 25, 2003.

Nancy E. Cheal,

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Current List of Laboratories Which Meet Minimum Standards To Engage in Urine Drug Testing for Federal Agencies

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

SUMMARY: The Department of Health and Human Services (HHS) notifies Federal agencies of the laboratories currently certified to meet the standards of Subpart C of the Mandatory Guidelines for Federal Workplace Drug Testing Programs (Mandatory Guidelines) published in the **Federal Register** on April 11, 1988 (53 FR 11970), and revised in the **Federal Register** on June 9, 1994 (59 FR 29908) and on September 30, 1997 (62 FR 51118). A notice listing all currently certified laboratories is published in the **Federal Register** during the first week of each month. If any laboratory's certification is suspended or revoked, the laboratory will be omitted from subsequent lists until such time as it is restored to full certification under the Mandatory Guidelines.

If any laboratory has withdrawn from HHS' National Laboratory Certification Program (NLCP) during the past month, it will be listed at the end, and will be omitted from the monthly listing thereafter.

This notice is also available on the Internet at <http://workplace.samhsa.gov> and <http://www.drugfreeworkplace.gov>

FOR FURTHER INFORMATION CONTACT: Mrs. Giselle Hersh or Dr. Walter Vogl, Division of Workplace Programs, 5600 Fishers Lane, Rockwall 2, Room 815, Rockville, Maryland 20857; 301-443-6014 (voice), 301-443-3031 (fax).

SUPPLEMENTARY INFORMATION: The Mandatory Guidelines were developed in accordance with Executive Order 12564 and section 503 of Pub. L. 100-71. Subpart C of the Guidelines, "Certification of Laboratories Engaged in Urine Drug Testing for Federal Agencies," sets strict standards that laboratories must meet in order to conduct urine drug testing for Federal agencies. To become certified, an applicant laboratory must undergo three rounds of performance testing plus an on-site inspection.

To maintain that certification, a laboratory must participate in a quarterly performance testing program plus periodic, on-site inspections.

Laboratories which claim to be in the applicant stage of certification are not to be considered as meeting the minimum requirements expressed in the HHS Mandatory Guidelines. A laboratory must have its letter of certification from HHS/SAMHSA (formerly: HHS/NIDA) which attests that it has met minimum standards.

In accordance with Subpart C of the Mandatory Guidelines, the following laboratories meet the minimum standards set forth in the Mandatory Guidelines:

ACL Laboratories,
8901 W. Lincoln Ave.,
West Allis, WI 53227,
414-328-7840/800-877-7016
(Formerly: Bayshore Clinical Laboratory);

ACM Medical Laboratory, Inc.,
160 Elmgrove Park,
Rochester, NY 14624,
585-429-2264;

Advanced Toxicology Network,
3560 Air Center Cove, Suite 101,
Memphis, TN 38118,
901-794-5770/888-290-1150;

Aegis Analytical Laboratories, Inc.,
345 Hill Ave.,
Nashville, TN 37210,
615-255-2400;

Alliance Laboratory Services,
3200 Burnet Ave.,
Cincinnati, OH 45229,
513-585-6870

(Formerly: Jewish Hospital of Cincinnati, Inc.);

Baptist Medical Center-Toxicology Laboratory,
9601 I-630, Exit 7,
Little Rock, AR 72205-7299,
501-202-2783

(Formerly: Forensic Toxicology Laboratory Baptist Medical Center);

Clinical Reference Lab,
8433 Quivira Rd.,
Lenexa, KS 66215-2802,
800-445-6917;

Diagnostic Services Inc., dba DSI,
12700 Westlinks Dr.,
Fort Myers, FL 33913,
239-561-8200/800-735-5416;

Doctors Laboratory, Inc.,
P.O. Box 2658, 2906 Julia Dr.,
Valdosta, GA 31602,
912-244-4468;

DrugProof, Division of Dynacare/Laboratory of Pathology, LLC,
1229 Madison St., Suite 500, Nordstrom Medical Tower,
Seattle, WA 98104,
206-386-2661/800-898-0180
(Formerly: Laboratory of Pathology of Seattle, Inc., DrugProof, Division of Laboratory of Pathology of Seattle, Inc.);

DrugScan, Inc.,
P.O. Box 2969, 1119 Mearns Rd.,
Warminster, PA 18974,
215-674-9310;

Dynacare Kasper Medical Laboratories*,
10150-102 St., Suite 200,
Edmonton, Alberta,
Canada T5J 5E2,
780-451-3702/800-661-9876;

ElSohly Laboratories, Inc.,
5 Industrial Park Dr.,
Oxford, MS 38655,
662-236-2609;
Express Analytical Labs,
3405 7th Ave., Suite 106,
Marion, IA 52302,
319-377-0500;

Gamma-Dynacare Medical Laboratories*,
A Division of the Gamma-Dynacare Laboratory Partnership,
245 Pall Mall St.,
London, ONT,
Canada N6A 1P4,
519-679-1630;

* The Standards Council of Canada (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.