includes an optional GHS hazard category that could be used to provide at least equivalent hazard labeling as current U.S. regulations in order to support continued protection of consumers and workers.

The ICCVAM TMER, *Current Validation Status of a Proposed In Vitro Testing Strategy for U.S. Environmental Protection Agency Ocular Hazard Classification and Labeling of Antimicrobial Cleaning Products* (NIH Publication No. 10–7513) provides ICCVAM's evaluation and recommendations regarding the use of a proposed in vitro testing strategy to classify and label AMCPs for eye irritation. ICCVAM concludes that the data are insufficient to adequately demonstrate that the proposed *in vitro* testing strategy can classify test substances to all four EPA ocular hazard categories. ICCVAM recommends further studies to characterize the usefulness and limitations of the non-animal *in vitro* testing strategy that uses the three in vitro test methods. This report also includes updated ICCVAM-recommended BCOP, CM, and EpiOcular™ test method protocols, the final summary review document (SRD), and the panel's peer review report.

The ICCVAM TMER, *Recommendation to Discontinue Use of the Low Volume Eye Test for Ocular Safety Testing* (NIH Publication No. 10–7515) provides ICCVAM's evaluation and recommendations on the usefulness of the LVET as an *in vivo* reference test method. ICCVAM concludes that the proposed LVET should not be used for regulatory safety testing due to performance issues.

Background Information on ICCVAM, NICEATM, and SACATM

ICCVAM is an interagency committee composed of representatives from 15 Federal regulatory and research agencies that require, use, or generate toxicological and safety testing information for chemicals, products, and other substances. ICCVAM conducts technical evaluations of new, revised, and alternative methods with regulatory applicability, and promotes the scientific validation and regulatory acceptance of toxicological and safety testing methods that more accurately assess the safety and health hazards of chemicals and products while reducing, refining (decreasing or eliminating pain and distress), or replacing animal use. The ICCVAM Authorization Act of 2000 (42 U.S.C. 285l–2, 285l–5 [2000], available at *http://iccvam.niehs.nih.gov/docs/about_docs/PL106545.pdf*) established ICCVAM as a permanent interagency committee of the NIEHS under NICEATM.

NICEATM administers ICCVAM, provides scientific and operational support for ICCVAM-related activities, and coordinates international validation studies of new and improved test methods. NICEATM and ICCVAM work collaboratively to evaluate new and improved test methods applicable to the needs of U.S. Federal agencies. NICEATM and ICCVAM welcome the public nomination of new, revised, and alternative test methods for validation studies as well as technical evaluations. Additional information about NICEATM and ICCVAM can be found on the NICEATM–ICCVAM Web site (*http://www.iccvam.niehs.nih.gov)*.

SACATM was established January 9, 2002, and is composed of scientists from the public and private sectors (67 FR 11358). SACATM provides advice to the Director of the NIEHS, ICCVAM, and NICEATM regarding the statutorily mandated duties of ICCVAM and activities of NICEATM. Additional information about SACATM, including the charter, roster, and records of past meetings, can be found at *http://ntp.niehs.nih.gov/go/167.*

References

ICCVAM. 2006. ICCVAM Test Method Evaluation Report: In Vitro Ocular Toxicity Test Methods for Identifying Severe Irritants and Corrosives. NIH Publication No. 07–4517. Research Triangle Park, NC: NIEHS. Available: *http://iccvam.niehs.nih.gov/methods/ocutox/ivocutox/ocu_tmer.htm.*

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ICCVAM. 2010. ICCVAM Test Method Evaluation Report: Recommendation to Discontinue Use of The Low Volume Eye Test for Ocular Safety Testing. NIH Publication No. 10–7515. Research Triangle Park, NC: NIEHS. Available: *http://iccvam.niehs.nih.gov/methods/ocutox/LVET.htm.*

Dated: September 10, 2010.

John R. Bucher,

Associate Director, National Toxicology Program.

[FR Doc. 2010–23262 Filed 9–16–10; 8:45 am]

BILLING CODE 4140–01–P

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 (SAMHSA) 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 (240) 276–1243.

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: Strategic Prevention Framework State Incentive Grant (SPF SIG) Program (OMB No. 0930–0279)—Revision

SAMHSA's Center for Substance Abuse Prevention (CSAP) is responsible for the evaluation instruments of the Strategic Prevention Framework State Incentive Grant (SPF SIG) Program. The program is a major initiative designed to: (1) Prevent the onset and reduce the progression of substance abuse, including childhood and underage drinking; (2) reduce substance abuse related problems; and, (3) build prevention capacity and infrastructure at the State-, territorial-, tribal- and community-levels.

Five steps comprise the SPF:

Step 1: Profile population needs, resources, and readiness to address the problems and gaps in service delivery.

Step 2: Mobilize and/or build capacity to address needs.

Step 3: Develop a comprehensive strategic plan.

Step 4: Implement evidence-based prevention programs, policies, and practices and infrastructure development activities.

Step 5: Monitor process, evaluate effectiveness, sustain effective programs/activities, and improve or replace those that fail.

An evaluation team is currently implementing a multi-method, quasi-experimental evaluation of the first two Strategic Prevention Framework State Incentive Grant (SPF SIG) cohorts receiving grants in FY 2004 and FY 2005. This notice invites comments for revision to the protocol for the ongoing cross-site evaluation for the Strategic Prevention Framework State Incentive Grant (SPF SIG) (OMB No. 0930–0279) which expires on 11/30/12. This revision includes two parts:

(1) Continuation of the use of the previously approved two-part Community Level Instrument (CLI Parts I and II) for Cohorts I and II and the use of an instrument to assess the sustainability of grantee implementation and infrastructure accomplishments which is a modification of an instrument used in an earlier phase of the evaluation.

(2) The use of three additional instruments to support the SPF SIG Cohorts III and IV Cross-site Evaluation. All three instruments are modified versions of data collection protocols used by Cohorts I and II. The three instruments are:

a. A Grantee-Level SPF Implementation Instrument,

b. A Grantee-Level Infrastructure Instrument, and

c. A two-part Community-Level SPF Implementation Instrument.

An additional Cohort III and IV evaluation component (*i.e.,* participant-level NOMs outcomes) is also included in this submission as part of the comprehensive evaluation, however, no associated burden from this evaluation activity is being imposed and therefore clearance to conduct the activities is not being requested. Specifically, Cohort III and IV SPF SIG grantees have been included in the currently OMB approved umbrella NOMs application (OMB No. 0930–0230) covering the collection of participant-level NOMs outcomes by all SAMHSA/CSAP grantees.

Every attempt has been made to make the evaluation for Cohorts III and IV comparable to Cohorts I and II. However, resource constraints for the Cohorts III and IV evaluation have necessitated some streamlining of the original evaluation design. Since the ultimate goal is to fund all eligible jurisdictions, there are no control groups at the grantee level for Cohorts III and IV. The primary evaluation objective is to determine the impact of SPF SIG on the reduction of substance abuse related problems, on building state prevention capacity and infrastructure, and preventing the onset and reducing the progression of substance abuse, as measured by the SAMHSA National Outcomes Measures (NOMs). Data collected at the grantee, community, and participant levels will provide information about process and system outcomes at the grantee and community levels as well as context for analyzing participant-level NOMS outcomes. The Grantee-Level Infrastructure and Implementation Instruments (Cohorts III and IV) and the Community-Level Part I and Part II (Cohorts I, II, III, and IV) Instruments are included in an OMB review package and are the main focus of this announcement.

Grantee-Level Data Collection

Cohort I and II Continuation

The Sustainability Interview will be conducted during Phase II of the evaluation in 2011 (Cohort I) and 2012 (Cohort II). The interview guide is adapted from the Phase I instruments (OMB No. 0930–0279) and focuses on state-level prevention capacity and infrastructure in relation to the five steps of the SPF process: Needs assessment, capacity building, strategic planning, implementation of evidence-based programs, policies, and practices (EBPPPs), and evaluation/monitoring. The interviews will be aimed at understanding the status of the prevention infrastructure at the time of the interview, whether the status has changed since the previous rounds of interviews (conducted in 2007 and 2009), and whether the SPF SIG had any influence on changes that might have occurred.

Cohort III and IV Revision

Two Grantee-level Instruments (GLI) were developed to gather information about the infrastructure of the grantee's overall prevention system and collect data regarding the grantee's efforts and progress in implementing the Strategic Prevention Framework 5-step process. Both instruments are modified versions of the grantee-level interview protocols used in the SPF SIG Cohort I and II Cross-Site Evaluation (OMB No. 0930–0279). The total burden imposed by the original interview protocols has been reduced by restructuring the format of the original protocol, deleting several questions and replacing the majority of open-ended questions with multiple-choice-response questions. The Infrastructure Instrument will capture data to assess infrastructure change and to test the relationship of this change to outcomes. The Strategic Prevention Framework Implementation Instrument will be used to assess the relationship between SPF implementation and change in the NOMs. Information for both surveys will be gathered by the grantees' evaluators twice over the life of the SPF SIG award.

Based on the current 16 grantees funded in Cohort III and an estimated 20 to be funded in Cohort IV the estimated annual burden for grantee-level data collection is displayed below in Table 1. The burden estimates for the GLIs are based on the experience in the Cohort I and II SPF SIG evaluation as reported in the original OMB submission (OMB No. 0930–0279), less the considerable reduction in length of these instruments implemented by the Cohort III and IV evaluation team.

Community-Level Data Collection (Continuation and Revision)

Cohort I and II Continuation

The Community-level Instrument (CLI) is a two part, web-based survey for capturing information about SPF SIG implementation at the community level (originally submitted as an addendum to OMB No. 0930–0279). Part I of this instrument was developed to assess the progress of communities as they implement the Strategic Prevention Framework (SPF), and Part II was developed to gather descriptive information about the specific

interventions being implemented at the community level and the populations being served including the gender, age, race, ethnicity, and number of individuals in target populations. Each SPF SIG funded community will complete a separate Part II form for each intervention they implement.

The CLI (Parts I and II) was designed to be administered two times a year (every six months) over the course of the SPF SIG Cohort I and II initiative. Four rounds of data were collected under the current OMB approval period and the Cohorts I and II cross-site evaluation team plans to collect additional rounds once this request for a revision is approved. Data from this instrument will allow CSAP to assess the progress of the communities in their implementation of both the SPF and prevention-related interventions funded under the initiative. The data may also be used to assess obstacles to the implementation of the SPF and prevention-related interventions and facilitate mid-course corrections for communities experiencing implementation difficulties.

The estimated annual burden for community-level data collection is displayed below in Table 1. Note that the total burden reflects the 443 communities that have received SPF funds from their respective Cohort I and Cohort 2 States. Burden estimates are based on pilot respondents' feedback as well as the experience of the survey developers reported in the original OMB submission (OMB No. 0930–0279). Additionally, an individual community's burden may be lower than the burden displayed in Table 1 because all sections of the Community-level Instrument (parts I and II) may not apply for each reporting period as community partners work through the SPF steps and only report on the step-related activities addressed. Note also that some questions will be addressed only once and the responses will be used to pre-fill subsequent surveys.

Cohort III and IV (Revision)

The Community-Level Instrument to be completed by Cohort III and IV funded subrecipient communities is a modified version of the one in use in the SPF SIG Cohorts I and II Cross-Site Evaluation (OMB No. 0930–0279). The total burden imposed by the original instrument was reduced by reorganizing the format of the original instrument, optimizing the use of skip patterns, and replacing the majority of open-ended questions with multiple-choice-response questions.

Part I of the instrument will gather information on the communities' progress implementing the five SPF SIG steps and efforts taken to ensure cultural competency throughout the SPF SIG process. Subrecipient communities receiving SPF SIG awards will be required to complete Part I of the instrument annually. Part 2 will capture data on the specific prevention intervention(s) implemented at the community level. A single prevention intervention may be comprised of a single strategy or a set of multiple strategies. A Part II instrument will be completed for each prevention intervention strategy implemented during the specified reporting period. Specific questions will be tailored to match the type of prevention intervention strategy implemented (*e.g.,* Prevention Education, Community-based Processes, and Environmental). Information collected on each strategy will include date of implementation, numbers of groups and participants served, frequency of activities, and gender, age, race, and ethnicity of population served/affected. Subrecipient communities' partners receiving SPF SIG awards will be required to update Part II of the instrument a minimum of every six months.

The estimated annual burden for specific segments of the community-level data collection is displayed in Table 1. The burden estimates for the CLIs are based on the experience in the Cohort I and II SPF SIG evaluation as reported in the original OMB submission (OMB No. 0930–0279), less the considerable reduction in length of these instruments implemented by the Cohort III and IV evaluation team. The total burden assumes an average of 15 community-level subrecipients per grantee (n=36 Grantees) for a total of 540 community respondents, annual completion of the CLI Part I, a minimum of two instrument updates per year for the CLI Part II, and an average of three distinct prevention intervention strategies implemented by each community during a 6-month period. Additionally, some questions will be addressed only once and the responses will be used to pre-fill subsequent updates.

Participant-Level Data Collection (Cohort III and IV—Continuation)

Participant-level change will be measured using the CSAP NOMs Adult and Youth Programs Survey Forms already approved by OMB (OMB No. 0930–0230). Subrecipient communities will have the opportunity to select relevant measures from the CSAP NOMs Adult and Youth Programs Survey Forms based on site-specific targeted program outcomes and may voluntarily select additional outcome measures that are relevant to their own initiatives. Cohort III and IV SPF SIG grantees have been included in the currently OMB approved umbrella NOMs application (OMB No. 0930–0230) covering all SAMHSA/CSAP grantees, therefore no additional burden for this evaluation activity is being imposed and clearance to conduct the activities is not being requested.

Total Estimates of Annualized Hour Burden

Estimates of total and annualized reporting burden for respondents by evaluation cohort are displayed below in Table 1. Overall summaries appear in Table 2. The estimated average annual burden of 5,642.9 hours is based on the completion of the Community Level-Instrument (CLI Parts I and II) and Sustainability Interview for Cohorts I and II, and the Grantee-level Instruments (GLI) and the Community-Level Instrument (CLI) for Cohorts III and IV.

TABLE 1—ESTIMATES OF ANNUALIZED HOUR BURDEN TO RESPONDENTS

Instrument	Respondent	Number of respondents	Number of responses per respondent (over four years)	Total number of responses (over four years)	Burden per response (hrs.)	Total burden (hrs.)
Cohorts 1 and 2—Grantee Level Burden						
CLI grantee input	Grantee	26	2	52	1	52.0
Sustainability Interview	Grantee	26	1	26	1.5	39.0

TABLE 1—ESTIMATES OF ANNUALIZED HOUR BURDEN TO RESPONDENTS—Continued

Instrument	Respondent	Number of respondents	Number of responses per respondent (over four years)	Total number of responses (over four years)	Burden per response (hrs.)	Total burden (hrs.)
Total Burden	Grantee	26	3	78	2.5	91.0
Average Annual Burden Over 4 Reporting years	Grantee	26				22.8
Cohorts 1 and 2—Community Level Burden						
CLI Part 1	Community	443	2	886	2.17	1,922.6
CLI Part 2	Community	443	8	3,544	2.17	7,690.5
Review of Past Responses	Community	443	2	886	2.50	2,215.0
Total Burden	Community	443	12	5,316	6.84	11,828.1
Average Annual Burden Over 4 Reporting years	Community	443				2,957.0
Cohorts 3 and 4—Grantee Level Burden						
GLI Infrastructure & Implementation Instruments (Reporting Years 1–4)	Grantee	36	2	72	4.75	342.0
CLI Part I, 1–20: Community Contact Information (Reporting Year 1)	Grantee	36	1	36	1.5	54.0
CLI Part I, 1–20: Community Contact Information (Reporting Years 2–4)	Grantee	36	3	108	0.25	27.0
Total Burden Over 4 Reporting Years	Grantee	36	6	216	6.5	423.0
Average Annual Burden	Grantee	9				105.8
Cohorts 3 and 4—Community Level Burden						
CLI Part I, 21–172: Community SPF Activities (Reporting Year 1)	Community	540	1	540	3	1,620.0
CLI Part II (Reporting Year 1)	Community	540	6	3,240	0.75	2,430.0
CLI Part I, 21–172: Community SPF Activities (Reporting Years 2–4)	Community	540	3	1,620	0.75	1,215.0
CLI Part II (Reporting Years 2–4)	Community	540	18	9,270	0.5	4,860.0
Total Burden Over 4 Years	Community	540	28	15,120	5	10,125.0
Average Annual Burden	Community	540				2,531.3

TABLE 2—ANNUALIZED SUMMARY TABLE

Respondents	Number of respondents	Responses/ respondent	Total responses	Total annualized hour burden
All Cohorts—Total Burden				
Cohort 1 and 2:				
Grantees	26	3	78	48.8
Community	443	12	5,316	2,957.0
Cohort 3 and 4:				
Grantees	36	6	216	105.8
Community	540	28	15,120	2,531.3
Sub-total Grantees	62			128.6
Sub-total Community	983			5,488.3
Total	1045		20,730	5,616.9

Send comments to Summer King, SAMHSA Reports Clearance Officer, Room 7–1044, One Choke Cherry Road, Rockville, MD 20857 and e-mail a copy to *summer.king@samhsa.hhs.gov.* Written comments should be received within 60 days of this notice.

Dated: September 10, 2010.

Elaine Parry,

Director, Office of Management, Technology and Operations.

[FR Doc. 2010–23207 Filed 9–16–10; 8:45 am]

BILLING CODE 4162–20–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Agency for Healthcare Research and Quality, HHS.

ACTION: Notice.

SUMMARY: This notice announces the intention of the Agency for Healthcare Research and Quality (AHRQ) to request that the Office of Management and Budget (OMB) approve the proposed information collection project: "Evaluation of the National Guideline Clearinghouse." In accordance with the Paperwork Reduction Act, 44 U.S.C. 3501–3520, AHRQ invites the public to comment on this proposed information collection.

DATES: Comments on this notice must be received by November 16, 2010.

ADDRESSES: Written comments should be submitted to: Doris Lefkowitz, Reports Clearance Officer, AHIRQ, by e-mail at *doris.lefkowitz@AHRQ.hhs.gov.*

Copies of the proposed collection plans, data collection instruments, and specific details on the estimated burden can be obtained from the AHRQ Reports Clearance Officer.

FOR FURTHER INFORMATION CONTACT: Doris Lefkowitz, AHRQ Reports Clearance Officer, (301) 427–1477, or by e-mail at *doris.lefkowitz@AHRO.hhs.gov.*

SUPPLEMENTARY INFORMATION:

Proposed Project

Evaluation of the National Guideline Clearinghouse

The mission of the Agency for Healthcare Research and Quality (AHRQ) is to enhance the quality, appropriateness, and effectiveness of Health services, and access to such services, through the establishment of a broad base of scientific research and through the promotion of improvements in clinical and health system practices, including the prevention of diseases and other health conditions. 42 U.S.C. 299(b). AHRQ supports the dissemination of evidence-based guidelines through its National Guideline Clearinghouse™ (NGC).

The NGC serves as a publicly accessible Web-based database of evidence-based clinical practice guidelines meeting explicit criteria. The NGC also supports AHRQ's strategic goal on effectiveness: to improve health care outcomes by encouraging the use of evidence to make informed health care decisions. The NGC is a vehicle for such encouragement. The mission of the NGC is to provide physicians, nurses, and other health professionals, health care providers, health plans, integrated delivery systems, purchasers and others an accessible mechanism for obtaining objective, detailed information on clinical practice guidelines and to further their dissemination, implementation and use.

AHRQ proposes to conduct a comprehensive evaluation of the NGC. This evaluation will build on the site trends AHIRQ has already identified, including growth from 70,000 to 700,000 visits per month, 600 to approximately 40,000 e-mail subscribers, 250 to 2,370 guidelines represented, and 50 to nearly 300 participating guideline developer organizations from July 1999 to July 2009.

The objectives of the NGC evaluation are to gain a better understanding of how:

- The NGC is used.
- The NGC supports dissemination of evidence-based clinical practice guidelines and related documents.
- The NGC has influenced efforts in guideline development and guideline implementation and use.
- The NGC can be improved.

This study is being conducted by AHRQ through its contractor, AFYA, Inc. and The Lewin Group (AFYA/Lewin), pursuant to AJ4RQ's statutory authority to conduct and support research and disseminate information on healthcare and on systems for the delivery of such care, including activities with respect to clinical practice. 42 U.S.C. 299a(a)(4).

Method of Collection

To achieve the objectives of this project the following data collections will be implemented:

(1) NGC evaluation survey—a web-based survey administered to a convenience sample of both users and non-users of the NGC,

(2) Focus groups—conducted with guideline developers, medical librarians, informatics specialists, clinicians, and students, and

(3) Key informant interviews—in-person interviews conducted with influential individuals in medical societies, health plans, and quality improvement organizations as well as medical librarians, researchers, and informatics specialists who produce, use, and disseminate guidelines.

Questions in the survey, focus group, and key informant discussion guides will focus on the effectiveness of NGC in areas of dissemination, implementation, and use of evidence-based clinical practice guidelines, and relative to other available guideline sources. For example, measures to be gathered through the instruments include the level of trust of the NGC, the use of the NGC relative to other guideline sources, and the influence of the NGC on various stakeholder groups. In addition, the instruments will be used to measure the use of other guideline resources which are used by non-NGC users.

Estimated Annual Respondent Burden

Exhibit 1 shows the estimated annualized burden hours for the respondents' time to participate in this evaluation. The NGC evaluation questionnaire will be completed by approximately 40,220 persons and will require 10 minutes to complete for users of the NGC and about 2 minutes for non-users. For the purpose of calculating respondent burden an average of 8 minutes is used and reflects a mix of users and non-users with most respondents expected to be users.

Eleven different focus groups consisting of 9 persons each will be conducted and are expected to last 90 minutes each. Key informant interviews will be conducted with 30 individuals and will last about 60 minutes. The total annual burden hours are estimated to be 5,542 hours.

Exhibit 2 shows the estimated annualized cost burden based on the respondents' time to participate in this project. The total annual cost burden is estimated to be $185,712.