FDA believes it needs additional information from stakeholders to effectively implement its new responsibilities with respect to waiver decisions. In particular, the agency needs to decide whether to continue to apply the current criteria, finalize the proposed rule published by CDC in 1995, or repropose other procedures and criteria for this process. FDA is inviting laboratory groups, medical professional societies, patient groups, manufacturers, manufacturing associations, and other interested parties to attend this open public workshop regarding the criteria for waiver. To the extent possible, oral and written testimony should address the following general and specific questions:

B. General Questions for Public Input

Criteria for waived tests under the Public Health Service Act were amended by FDAMA to read: Waived tests ''are laboratory examinations and procedures that have been approved by Food and Drug Administration for home use or that, as determined by the Secretary, are simple laboratory examinations and procedures that have an insignificant risk of an erroneous result, including those that (A) employ methodologies that are so simple and accurate to render the likelihood of erroneous results by the user negligible, or (B) the Secretary has determined pose no unreasonable risk of harm to the patient if performed incorrectly * * *.''

1. What criteria should be used to demonstrate that a waived test is a simple laboratory examination and procedure with ''an insignificant risk of an erroneous result?'' For example:

a. Should a waived test, when performed by untrained users, provide an accurate result with no significant clinical or statistical error when compared to a measure of truth? This requires availability of well-characterized reference methods and/or materials as part of the waived test assessment. The current threshold for waiver as established by CDC is no significant inaccuracy and no significant imprecision.

b. Should a waived test, when performed by untrained users, provide a test result that shows no user error when compared to the same test performed in a CLIA certified lab by a trained user? This requires comparison of the test in a lay-user setting with performance of the test in a CLIA certified lab by a trained user. The threshold for waiver would be no difference in performance in the two settings.

c. Should FDA apply a different model to determine the waived status of a test?

2. What criteria should FDA use to determine if a methodology is ''so simple and accurate to render the likelihood of erroneous results by the user negligible?''

a. Should a waived test be so accurate when performed by untrained users that inaccurate results will not occur?

b. Should a waived test have variable accuracy if used adjunctively? Is it acceptable to waive tests that have inaccurate results but do not have any major negative clinical impact? How should FDA make this assessment?

3. What criteria should FDA use in determining that a test will ''pose no unreasonable risk of harm to the patient if performed incorrectly?''

4. Should the waiver process be different for screening tests that require a second test for confirmation? Because there are no CLIA standards for performance of waived testing, except instructions to follow the manufacturer's package insert, what is the assurance that confirmatory testing will be performed? Should the need for confirmatory testing raise, lower, or have no impact on the threshold for a waiver decision?

C. Specific Questions for Public Input

5. Should accuracy be determined using comparison of the waiver test to a well-characterized reference method and/or materials, to a designated comparative method and/or materials, to a working laboratory method and/or materials, to a clinical algorithm for diagnosis, and/or to other endpoints?

6. How many samples, what types of samples (real or artificial), by how many users and how many sites are appropriate to evaluate accuracy? (Current guidelines being followed by FDA are for performance to be demonstrated by laboratory users at a minimum of one site.)

7. What should be the background of these users?

8. What performance criteria (statistical or clinical) should FDA apply to the accuracy threshold for a waived test (e.g., t- test or McNemar test at key decision points, description of performance with confidence intervals at key decision points, use of set performance standards using a receiver operator curve–80 percent, 90 percent, 95 percent, or other–at key decision points, and/or others)?

9. How should FDA define precision for purposes of waiver determination? What types of samples, how many and what types of operators/sites are appropriate? Current CDC recommendation is for 20 samples at three levels representing appropriate decision points to be tested at three sites by lay users using materials in either artificial and/or real matrices depending on availability and biohazard issues.

10. What performance thresholds should FDA use to determine whether the precision studies are appropriate for waiver status (e.g., ANOVA (analysis of variance) analysis, use of a predefined performance goal, such as Tonks' formula, or percent agreement out of total repeat runs)?

11. What interference studies are appropriate to establish performance of waived tests (e.g., effects of hemolysis, lipemia, etc.)?

12. What environmental studies or flex (stress) studies are appropriate to establish performance of waived tests (e.g., temperature or humidity stresses, short fills)?

13. What additional studies (if any) should be submitted for evaluation of qualitative tests for waiver?

14. What additional studies (if any) should be submitted for evaluation of quantitative tests for waiver?

This will be an informal meeting conducted in accordance with 21 CFR 10.65.

Dated: July 14, 2000.

Lillian J. Gill,

Acting Deputy Director for Science, Center for Devices and Radiological Health.

[FR Doc. 00–18456 Filed 7–20–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish a list of information collection requests under OMB review, in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these documents, call the SAMHSA Reports Clearance Officer on (301)443-7978.

National Cross-Site Assessment of the Addiction Technology Transfer Centers Network—(New)

The Substance Abuse and Mental Health Administration's (SAMHSA) Center for Substance Abuse Treatment (CSAT) intends to conduct an assessment of its Addiction Technology Transfer Centers (ATTCs). The goal

underlying the training and education opportunities provided through the ATTCs is to enhance the competencies of professionals in a variety of disciplines to address the clinical needs of individuals with substance abuse problems using research-based curricula and training materials through both traditional and non-traditional technologies.

The ATTCs disseminate current health services research from the National Institute on Drug Abuse, National Institute on Alcohol Abuse and Alcoholism, National Institute of Mental Health, Agency for Health Care Policy and Research, National Institute of Justice, and other sources and applied knowledge development activities from SAMHSA using innovative technologies by developing and updating state-of-the-art research-based curricula and developing faculty and trainers. Participants in ATTC training events are self-identified and participate in either academic courses or continuing education/professional development training events. Academic courses are offered at all levels. Continuing education/professional development training is designed to meet identified needs of counselors and other professionals who work with individuals with substance abuse problems.

Both a process and an outcome assessment will be conducted. The process component will describe the training and education needs of pre-service and currently practicing professionals, the types of training events that students/trainees receive through the ATTCs, and student/trainee satisfaction with services. The outcome component will focus on changes in clinical practice made by trainees as a result of knowledge received.

Analysis of this information will assist CSAT in documenting the numbers and types of participants in ATTC education/training offerings, describing the extent to which participants improve in their clinical competency, and which method is most effective in disseminating knowledge to the various audiences. This type of information is crucial to support CSAT in complying with GPRA reporting requirements and will inform future development of knowledge dissemination activities.

The study design for students and trainees will include a description of each course/training event, and a pre-post design that collects identical information at initiation of ATTC courses/trainings, at the completion of the course/training, and again after 3 months. This time frame is necessary to allow students/trainees the opportunity to implement changes in clinical practice. In addition, the study will collect satisfaction measures after each course/training event.

The chart below summarizes the annualized burden for this project.

Respondent type	Number of respondents	Average responses/ respondent	Average time/ response (hours)	Annual burden (hours)
Students/trainees	12,000	4	.52	6,240
Faculty/trainers	195	1	.25	49
ATTC summary reports	13	4	2.00	104
Total	12,208			6,393

Written comments and recommendations concerning the proposed information collection should be sent within 30 days of this notice to: SAMHSA Desk Officer, Human Resources and Housing Branch, Office of Management and Budget, New Executive Office Building, Room 10235, Washington, D.C. 20503.

Dated: July 16, 2000.

Richard Kopanda,

Executive Officer, SAMHSA.

[FR Doc. 00–18484 Filed 7–20–00; 8:45 am]

BILLING CODE 4162–20–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–4562–N–06]

Notice of Proposed Information Collection for Public Comment: Doctoral Dissertation Research Grant Program

AGENCY: Office of the Assistant Secretary for Policy Development and Research, HUD.

ACTION: Notice.

SUMMARY: The proposed information collection requirement described below will be submitted to the Office of Management and Budget (OMB) for review, as required by the Paperwork Reduction Act. Public comments on the subject proposal are being solicited.

DATES: *Comments Due Date:* September 19, 2000.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name or OMB control number and be sent to: Reports Liaison Officer, Office of Policy Development and Research, Department of Housing and Urban Development, 451 7th Street, SW, Room 8226, Washington, DC 20410.

FOR FURTHER INFORMATION CONTACT: Jane Karadbil, Office of University Partnerships, Department of Housing and Urban Development, 451 7th Street, Washington, DC 20410; telephone (202) 708–1537 (this is not a toll-free number). Copies of the proposed forms and other available documents to be submitted to OMB may be obtained from Ms. Karadbil.

SUPPLEMENTARY INFORMATION: The Department will submit the proposed information collection to OMB for review, as required by the Paperwork Reduction Action of 1995 (44 U.S.C. Chapter 35, as amended).

This Notice is soliciting comments from members of the public and affected entities concerning the proposed information collection 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 information to be collected; and (4) Minimize the burden of collection of information on those who are to respond; including through the use of appropriate technology, *e.g.,* permitting electronic submission of responses.

This Notice also lists the following information:

Title of the Proposal: Doctoral Dissertation Research Grant Program (DDRG).

Description of the need for the information and proposed use: The information is being collected to enable HUD to select grantees in this competitive grant program. The information is also being used to monitor the performance of grantees to