

this guidance was approved under OMB Control No. 0910-0001 and 0910-0032.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the agency's current thinking on these topics. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may at any time submit to the Division of Dockets Management written or electronic comments on the guidance (see **ADDRESSES**). Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The guidance and received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the document at either <http://www.fda.gov/cder/guidance/index.htm> or <http://www.fda.gov/ohrms/dockets/default.htm>.

Dated: November 13, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04-25748 Filed 11-19-04; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

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

Periodically, the Health Resources and Services Administration (HRSA) publishes information collection requests under review by the Office of Management and Budget, in compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35). To request a copy of the clearance requests submitted to OMB for review, call the HRSA Reports Clearance Office on (301) 443-1129.

The following request has been submitted to the Office of Management and Budget for review under the Paperwork Reduction Act of 1995:

Proposed Project: The Division of Independent Review Grant Reviewer Recruitment Form—New

HRSA's Division of Independent Review (DIR) is responsible for carrying out the independent review of all eligible applications submitted to HRSA. DIR ensures that the independent review process is efficient, effective, economical and complies with statutes, regulations and policies. The review of applications is performed by people knowledgeable in the field of endeavor for which support is requested and is advisory to individuals in HRSA responsible for making award decisions.

To streamline the collection, selection and assignment of grant reviewers to independent review committees, HRSA will utilize a Web-based data collection form to gather critical reviewer information. The Grant Reviewer Recruitment Form will standardize pertinent categories of reviewer information, such as areas of expertise, occupations, work settings, reviewer experience, and allow maximum use of drop-down menus to simplify for the data collection process. All self-nominated reviewers will be channeled to the Grant Reviewer Recruitment Form. DIR anticipates a monthly volume of approximately 100 self-nominated responses. On a periodic basis, existing HRSA reviewers will be notified and directed to update their profile (via the Grant Reviewer Recruitment Form). HRSA maintains a pool of approximately 5,000 individuals that have previously served on HRSA independent review committees. DIR projects that approximately 3,700 individuals (or 75% of existing reviewers) would comply with instructions to update their profile on the Web-based Recruitment Form.

For existing HRSA reviewers, the amount of time required to complete the Recruitment Form will be abbreviated since HRSA will fill in the Form with previously collected personal information; existing reviewers will focus only on updating changes (e.g., addresses, employer, expertise, occupation) to their profile. The estimate of burden for the HRSA Grant Reviewer Recruitment Form is as follows:

Type of respondent*	Number of respondents	Responses per respondent	Total responses	Minutes per response	Total burden hours
New reviewer	1,200	1	1,200	45	900
Existing reviewer	3,700	1	3,700	30	1850
Total	4,900		4,900		2,750

* Includes two categories of grant reviewers: (1) new or self-nominated reviewers that have never served as a HRSA grant reviewer and (2) existing reviewers that have previously served on a HRSA independent review committee.

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

Dated: November 15, 2004.

Tina M. Cheatham,

Director, Division of Policy Review and Coordination.

[FR Doc. 04-25751 Filed 11-19-04; 8:45 am]

BILLING CODE 4165-15-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Cooperative Agreement for the International AIDS Education and Training Center; CFDA 93.145

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice of supplemental award.

Intended Recipient of the Award: University of Washington, Seattle, Washington.

Purpose of the Award: This notice announces the program expansion supplement for the cooperative agreement for the International AIDS Education and Training Center at the University of Washington, Seattle, Washington, to expand and augment capacity building under the President's Emergency Plan for AIDS Relief (the President's Emergency Plan). This is the third budget period for this Cooperative Agreement. The purpose of this funding is to support the President's Emergency Plan by strengthening human and organizational capacity through training, technical assistance, infrastructure building, and curriculum development in the 15 focus countries including 12 in Africa, two in the Caribbean and Vietnam (Botswana, Côte d'Ivoire, Ethiopia, Guyana, Haiti, Kenya, Mozambique, Namibia, Nigeria, Rwanda, South Africa, Tanzania, Uganda and Zambia). Further training and technical assistance is also being augmented through the President's Emergency Plan in other countries for which bilateral agreements for similar strategies have been established. The President's Emergency Plan is intended to complement other bilateral and international support efforts, including support through the Global Fund to Fight AIDS, Tuberculosis, and Malaria.

Amount of the Award: \$8,877,718.

Project Period: Original Project Period 04/01/02–9/30/05, New Project Period: 04/01/02–2/28/06.

The current budget period is being extended to February 28, 2005 (in line with the intent of the five year strategy of the President's Emergency Plan). This would also extend the project period for the cooperative agreement from September 30, 2005, to February 28, 2006.

Justification for the Exception to Competition: The International AIDS Education and Training Center is the only Health Resources and Services Administration (HRSA), HIV/AIDS Bureau grantee providing valuable capacity building in the area of care and treatment to the focus and bilateral countries through training and other technical assistance. The original intent of this cooperative agreement was to fulfill the gap in training for quality, comprehensive HIV/AIDS care and treatment left by other U.S. Government partners. The President's Emergency Plan is providing the resources to provide the services that are needed in countries hardest hit by the AIDS epidemic. Without this program expansion supplement, HRSA's HIV/

AIDS Bureau will be unable to provide this enhanced level of resources and expertise to the targeted countries.

FOR FURTHER INFORMATION CONTACT:

Additional information on the International AIDS Education and Training Center may be obtained from Thurma Goldman, MD, MPH, HIV/AIDS Bureau, HRSA, 5600 Fishers Lane, Parklawn Building, Room 7-05, Rockville, Maryland 20857; telephone number (301) 443-1993; fax (301) 443-9645; or e-mail tgoldman@hrsa.gov.

Dated: November 10, 2004.

Elizabeth M. Duke,

Administrator.

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DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[USCG-2004-19665]

Towing Safety Advisory Committee

AGENCY: Coast Guard, DHS.

ACTION: Notice of meeting.

SUMMARY: The Towing Vessel Inspection Working Group of the Towing Safety Advisory Committee (TSAC) will meet to discuss matters relating to the inspection of towing vessels and safety management systems. The meetings will be open to the public.

DATES: The Towing Vessel Inspection Working Group will meet on Wednesday, December 8, 2004 from 1:30 p.m. to 4:30 p.m. and on Thursday, December 9, 2004 from 8:30 a.m. to 2 p.m. The meetings may close early if all business is finished. Written or electronic material and requests to make oral presentations should reach the Coast Guard on or before December 3, 2004. Requests to have a copy of your material distributed to each member of the Working Group should be in electronic form and reach the Coast Guard on or before December 3, 2004.

ADDRESSES: The Working Group will meet in the 7th Floor All-Hands Conference Room (#725), National Pollution Funds Center, 4200 Wilson Boulevard, Arlington, VA 22203. Please bring a government-issued ID with photo (e.g., driver's license). Send written or electronic material and requests to make oral presentations to Mr. Gerald Miente, Commandant (G-MSO-1), U.S. Coast Guard Headquarters, 2100 Second Street SW., Washington, DC 20593-0001. This notice and related documents are

available on the Internet at <http://dms.dot.gov> under the docket number USCG-2004-19665.

FOR FURTHER INFORMATION CONTACT: Mr. Gerald Miente, Assistant Executive Director of TSAC, telephone 202-267-0214, fax 202-267-4570, or e-mail gmiente@comdt.uscg.mil.

SUPPLEMENTARY INFORMATION: Notice of these meetings is given under the Federal Advisory Committee Act, 5 U.S.C. App. 2 (Pub. L. 92-463, 86 Stat. 770, as amended).

Agenda of Working Group Meetings

The agenda for the Towing Industry Safety System Working Group tentatively includes the following items:

(1) Identify the elements that should be included in a safety management system (SMS) requirement for towing vessels.

(2) Identify a framework for Coast Guard oversight and enforcement of a towing vessel inspection program based on a SMS and consider the role of third parties in such a system.

(3) Identify whether any towing vessel should be exempt from coverage under an inspection program based on a SMS.

(4) Identify proposed regulations implementing an inspection program for towing vessels based on a SMS.

Procedural

The meetings are open to the public. Please note that the meetings may close early if all business is finished. At the Chair's discretion, members of the public may make oral presentations during the meeting. If you would like to make an oral presentation at the meeting, please notify the Assistant Executive Director (as provided above in **FOR FURTHER INFORMATION CONTACT**) no later than December 3, 2004. Written or electronic material for distribution at the meeting should reach the Coast Guard no later than December 3, 2004.

Information on Services for Individuals With Disabilities

For information on facilities or services for individuals with disabilities or to request special assistance at the meeting, contact Mr. Miente at the number listed in **FOR FURTHER INFORMATION CONTACT** as soon as possible.

Dated: November 15, 2004.

Joseph J. Angelo,

Director of Standards, Marine Safety, Security & Environmental Protection.

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