

DATES: Written comments by October 1, 1997.

ADDRESSES: Submit written requests for single copies of "General Principles of Software Validation" to the Division of Small Manufacturers Assistance (HFZ-220), Center for Devices and Radiological Health (CDRH), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-0806 (outside MD 1-800-638-2041). Send two self-addressed adhesive labels to assist that office in processing your requests. Submit written comments on "General Principles of Software Validation" to the Dockets Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1-23, Rockville, MD 20857. Requests and comments should be identified with the docket number found in brackets in the heading of this document. A copy of "General Principles of Software Validation" and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: E. Stewart Crumpler, Center for Devices and Radiological Health (HFZ-343), Food and Drug Administration, 2094 Gaither Rd., Rockville, MD 20850, 301-594-4659.

SUPPLEMENTARY INFORMATION: This guidance outlines general validation principles that FDA considers to be applicable to the validation of medical device software or the validation of software used to design, develop, or manufacture medical devices. This guidance discusses how the general provisions of the Quality System Regulation apply to software and the agency's current approach to evaluating a software validation system. For example, this guidance lists validation elements which are acceptable to FDA for the validation of software, however, it does not list all of the activities and tasks that must in all instances, be used to comply with the law. An alternative approach may be used if such approach satisfies applicable statutory and regulatory requirements.

This guidance does not recommend any specific life cycle model or any specific validation technique or method, but does recommend that software validation activities be conducted throughout the entire software life cycle. For each software project, the responsible party should determine and justify the level of validation effort to be applied, and the specific combination of validation techniques to be used.

The guidance in this document is based on generally recognized software validation processes and could therefore be applicable to any software. For FDA purposes, this guidance is applicable to any regulated medical device related software as defined by the Federal Food, Drug, and Cosmetic Act or by current FDA software and regulatory policy. It is not the intent of this document to determine or identify specifically which software is or is not regulated.

This guidance represents the agency's current thinking on general principles of software validation. 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 statute, regulations, or both.

Interested persons may, on or before October 1, 1997, submit to the Dockets Management Branch (address above) written comments on "General Principles of Software Validation." Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. "General Principles of Software Validation" and received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday. Persons with access to the Internet may obtain the new draft guidance via the World Wide Web (WWW) at "<http://www.fda.gov/cdrh/comp/swareval.html>". The new draft guidance may also be obtained by calling the CDRH Facts-On-Demand system at 800-899-0381 or 301-827-0111 from a fax machine with a touch-tone telephone attached or built in. At the first voice prompt press 1 to access

DSMA Facts, at the second voice prompt press 2, and enter Shelf number 938 followed by the pound sign (#). Then follow the remaining voice prompts to complete your request.

Dated: July 15, 1997.

Elizabeth D. Jacobson,

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

[FR Doc. 97-19611 Filed 7-24-97; 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) 443-0525.

National Household Survey on Drug Abuse: ACASI Field Test 2—New—The Substance Abuse and Mental Health Services Administration (SAMHSA) will conduct a field test in October–December, 1997, to examine alternative designs for an Audio Computer Assisted Self-Interview (ACASI) version of the National Household Survey on Drug Abuse (NHSDA) questionnaire. The experimental design will compare variations in skip patterns, automatic internal consistency checks, number of chances to report use of substance. The basic questionnaire content will be identical to the 1997 NHSDA questionnaire. Approximately 2,300 interviews will be conducted with persons age 12 and older. A standardized set of respondent debriefing questions will be administered to the field test sample and to 750 respondents to the ongoing 1997 NHSDA. The estimated response burden for the field test is shown below:

	No. of respondents	Responses per respondent	Hours per response	Total burden hours
Electronic Household Screener	16,179	1	0.05	809
Electronic Questionnaire, Debriefing and Verification Form	2,256	1	0.92	2,076
Screening Verification	485	1	0.067	33
Interview Verification	338	1	0.067	23
Debriefing Questions for 1997 NHSDA Respondents	750	1	0.12	90
Total				3,031

Written comments and recommendations concerning the proposed information collection should be sent within 30 days of this notice to: Virginia Huth, Human Resources and Housing Branch, Office of Management and Budget, New Executive Office Building, Room 10236, Washington, D.C. 20503.

Dated: June 16, 1997.

Richard Kopanda,

Executive Officer, SAMHSA.

[FR Doc. 97-19604 Filed 7-24-97; 8:45 am]

BILLING CODE BILLING CODE: 4162-20-P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR-4235-N-13]

Federal Property Suitable as Facilities To Assist the Homeless

AGENCY Office of the Assistant Secretary for Community Planning and Development, HUD.

ACTION: Notice.

SUMMARY: This Notice identifies unutilized, underutilized, excess, and surplus Federal property reviewed by HUD for suitability for possible use to assist the homeless.

EFFECTIVE DATE: July 25, 1997.

FOR FURTHER INFORMATION CONTACT.

Mark Johnston, Department of Housing and Urban Development, Room 7256, 451 Seventh Street SW., Washington, DC 20410; telephone (202) 708-1226; TDD number for the hearing- and speech-impaired (202) 708-2565, (there telephone numbers are not toll-free), or call the toll-free Title V information line at 1-800-927-7588.

SUPPLEMENTARY INFORMATION: In accordance with December 12, 1988 court order in *National Coalition for the Homeless v. Veterans Administration*, No. 88-2503-OG (D.D.C.), HUD publishes a Notice, on a weekly basis, identifying unutilized, underutilized, excess and surplus Federal buildings and real property the HUD has reviewed for suitability for use to assist the homeless. Today's Notice is for the purpose of announcing that no additional properties have been determined suitable or unsuitable this week.

Dated: July 17, 1997.

Fred Karnas, Jr.,

Acting Deputy Assistant Secretary for Economic Development.

[FR Doc. 97-19581 Filed 7-24-97; 8:45 am]

BILLING CODE 4210-29-M

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR-4196-N-04]

Combined Notices of Funding Availability for FY 1997 for the Public and Indian Housing Economic Development and Supportive Services Program and the Tenant Opportunities Program

AGENCY: Office of the Assistant Secretary for Public and Indian Housing, HUD.

ACTION: Notice of Funding Availability (NOFA); clarification.

SUMMARY: This notice reaffirms a requirement set forth in the Fiscal Year (FY) 1997 NOFA for the Tenant Opportunities Program (TOP), published in the **Federal Register** on June 6, 1997 (62 FR 31272). Specifically, this notice reminds Intermediary Resident Organizations that they must provide letters of support from all Resident Associations they propose to assist as part of their applications. Although this requirement was set forth in the June 6, 1997 NOFA, it was inadvertently omitted from the TOP Application Kit.

DATES: This original deadline date is not changed. Applications must be received on or before August 13, 1997, at the correct local HUD Field Office or Area Office of Native American Programs (AONAP) having jurisdiction over the applicant by 3 p.m. (local time).

FOR FURTHER INFORMATION CONTACT: *For Public Housing:* Office of Resident Involvement, Office of Public and Indian Housing, Department of Housing and Urban Development, 451 Seventh Street, S.W. Washington, DC 20410; telephone number, (202) 708-3611 (This is not a toll-free number).

For Indian Housing: Tracy Outlaw, National ONAP, 1999 Broadway, Suite 3390, Denver, CO 80302; telephone number, (303) 675-1600 (This is not a toll-free number).

Hearing or speech-impaired persons may access these numbers via TTY by calling the toll-free Federal Information Relay Service at 1-800-877-8339.

SUPPLEMENTARY INFORMATION: On June 6, 1997 (62 FR 31272), HUD published a combined NOFA for the Public and Indian Housing Economic Development and Supportive Services Program and the Tenant Opportunities Program (TOP). The June 6, 1997 NOFA required that Intermediary Resident Organizations applying for TOP funds must provide letters of support from all Resident Associations they propose to assist as part of their applications.

Specifically, section VII(g)(10) of the NOFA provided that "[a]pplicants which are Intermediary Resident Organizations * * * must provide letters of support from each [Resident Association] identified in the application" (62 FR 31287).

Section III of the June 6, 1997 NOFA directed applicants to complete their applications in accordance with further guidance to be provided in an Application Kit (See 62 FR 31274). The Application Kit was printed following publication of the June 6, 1997 NOFA publication and has been widely distributed. In providing application formats, the Application Kit was designed to reflect NOFA requirements. The June 6, 1997 NOFA is also included as an attachment to the Application Kit.

HUD is concerned that, except for including the June 6, 1997 NOFA as an attachment, the Application Kit otherwise does not reference the requirement that Intermediary Resident Organizations provide letters of support from all Resident Associations to be assisted by TOP grant funds. Notwithstanding this omission, the June 6, 1997 NOFA is clear in requiring such letters. This requirement, like other threshold requirements listed in section VII(g) of the June 6, 1997 NOFA, must be satisfied in order for an application from an Intermediary Resident Organization to be complete and acceptable for rating and ranking.

Dated: July 17, 1997.

Kevin Emanuel Marchman,

Acting Assistant Secretary for Public and Indian Housing.

[FR Doc. 97-19582 Filed 7-24-97; 8:45 am]

BILLING CODE 4210-33-P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[WO-320-1330-01-24 1A]

Extension of Currently Approved Information Collection

OMB Approval Number 1004-0073

Information Collection Submitted to the Office of Management and Budget for Review Under the Paperwork Reduction Act.

The proposed renewal for the collection of information listed below has been submitted to the Office of Management and Budget for approval under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35). On April 14, 1997, the BLM published a notice in the **Federal Register** (62 FR 11842) requesting comments on the collection. The comment period ended