Filed Name	Comments
Record Identifier	Enter 'W4' for the W4 record. Enter 'QW' for the Quarterly Wage record. Enter 'UI' for the Unemployment Insurance record.
Foreign Address Data Elements.	If an address supplied for the employee or employer is outside the United States, include the Foreign Country Code for the address, the Foreign Country Name, and the Foreign Zip Code.
Employee Wage Amount (QW).	For Quarterly Wage data, provide the gross amount paid to the employee during the quarter, regardless of when the amount was earned.
Reporting Period	Use the quarters that correspond to the calendar year rather than quarters that correspond to fiscal accounting periods. Use the format QYYYY where Q=1 for January–March. Q=2 for April–June. Q=3 for July–September. Q=4 for October–December.
Benefit Amount (UI)	The UI Benefit Amount is the gross amount paid within the reporting quarter before any withholding offsets are applied. This amount should be the sum of benefits received from all programs tracked electronically by the State. However, only include those benefits that are housed in the same hardware environment. Do not include benefits from sources that must be translated or imported to the mainframe environment.

Output Records

FPLS will return records to the data transmitters when errors were detected. The states can elect to have these records returned for error resolution or not as they choose. Federal agencies, however, will receive all error records from each transmittal.

The record formats for the error records are identical to the input record provided by the submitter except that error codes will be appended that explain the nature of the error. Errors can occur at the transmission level and at the individual record level.

Transmission Control Records

This is the output equivalent of the input TRANSMITTER RECORD and includes counts of records received, records rejected, error records returned, records posted to the National Directory of New Hires, records posted to the Suspense File, and up to five Error Codes pertaining to the transmission level error conditions encountered.

Data Records

Each output version of the input DATA RECORD had appended to it up to five record level error codes that indicate the nature of the error encountered during editing. It also contains a Social Security Number Verification Indicator that indicates whether multiple valid SSNs were encountered during the SSN verification process. In addition, a corrected SSN is returned if during the SSN verification process the supplied SSN was determined to be incorrect and the verification procedure was able to provide the correct SSN.

Total Records

No transmission total records will be returned to the submitting State or federal agency.

In compliance with the requirements of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above.

The Department specifically requests comments on: (a) Whether the proposed collection of information is 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) 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. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Information Services, Division of Information Resource Management Service, Attn: ACF Reports Clearance Officer, 370 L'Enfant Promenade, S.W., Washington, D.C. 20447 or e-mail to Internet address: rdriscoll@acf.dhhs.gov. All requests should be identified by the title of the information collection.

Dated: July 18, 1997.

Robert Driscoll,

Reports Clearance Officer.

[FR Doc. 97–19494 Filed 7–24–97; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97D–0282]

General Principles of Software Validation; Draft Guidance; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance entitled ''General Principles of Software Validation.'' This guidance is applicable to medical device software and to 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.

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 Questionaire, 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