

Manufacturers Assistance (HFZ-220), Center for Devices and Radiological Health (CDRH), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send two self-addressed adhesive labels to assist that office in processing your request, or fax your request to 301-443-8818. Submit written comments concerning this draft guidance to the Dockets Management Branch (HFA 305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Comments should be identified with the docket number found in brackets in the heading of this document. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the draft guidance.

**FOR FURTHER INFORMATION CONTACT:** Charles A. Finder, Center for Devices and Radiological Health (HFZ 240), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 301-594-3332.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

The MQSA was passed on October 27, 1992, to establish national quality standards for mammography. After October 1, 1994, the MQSA required all mammography facilities, except facilities of the U.S. Department of Veterans Affairs, to be accredited by an approved accreditation body and certified by the Secretary of Health and Human Services (the Secretary). The authority to approve accreditation bodies and to certify facilities was delegated by the Secretary to FDA. In the **Federal Register** of October 28, 1997 (62 FR 55976), FDA published the MQSA final regulations. The final regulations became effective April 28, 1999, and replaced the interim regulations (58 FR 67558 and 58 FR 67565, December 21, 1993). Development of this guidance document began in December 1999.

**II. Significance of Guidance**

This draft guidance document represents the agency's current thinking on the final regulations implementing the MQSA. 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 applicable statute, regulations, or both.

The agency has adopted good guidance practices (GGP's), which set forth the agency's policies and procedures for the development, issuance, and use of guidance documents (62 FR 8961, February 27, 1997). This draft guidance document is

issued as a Level 1 guidance consistent with GGP's.

**III. Electronic Access**

In order to receive the draft guidance entitled "Compliance Guidance: The Mammography Quality Standards Act Final Regulations Document #4" via your fax machine, call the CDRH Facts-On-Demand system at 800-899-0381 or 301-827-0111 from a touch-tone telephone. At the first voice prompt press 1 to enter the system. At the second voice prompt press 1 to order a document. Enter the document number (1159) followed by the pound sign (#). Follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the draft guidance may also do so using the Internet. CDRH maintains an entry on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer with access to the Internet. Updated on a regular basis, the CDRH home page includes "Compliance Guidance: The Mammography Quality Standards Act Final Regulations Document #4," device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturers' assistance, information on video conferencing and electronic submissions, mammography matters, and other device-oriented information. The CDRH home page may be accessed at <http://www.fda.gov/cdrh>. "Compliance Guidance: The Mammography Quality Standards Act Final Regulations Document #4" will be available at <http://www.fda.gov/cdrh/mammography>.

**IV. Comments**

Interested persons may submit to Dockets Management Branch (address above) written comments regarding this draft guidance by December 12, 2000. Two copies of any comments are to be submitted, except that individual may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The draft guidance document and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 29, 2000.

**Linda S. Kahan,**

*Deputy Director for Regulations Policy, Center for Devices and Radiological Health.*

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**BILLING CODE 4160-01-F**

**DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT**

[Docket No. FR-4565-N-22]

**Notice of Proposed Information Collection: Comment Request; Multifamily Coinsurance Claims Package, Section 223(f)**

**AGENCY:** Office of the Assistant Secretary for Housing, 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. The Department is soliciting comments on the subject proposal.

**DATES:** *Comments due date:* November 13, 2000.

**ADDRESSES:** Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB Control Number and should be sent to Wayne Eddins, Reports Management Officer, Department of Housing and Urban Development, 451 7th Street, SW., L'Enfant Plaza Building, Room 8100, Washington, DC 20410.

**FOR FURTHER INFORMATION CONTACT:** Steven A. Trojan, Systems Accountant, Office of Financial Services, 451 7th Street, SW., Washington, DC 20410, telephone (202) 401-2168, extension 2823 (this is not a toll free number) for copies of the proposed forms and other available information.

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

This notice is soliciting comments from members of the public and affected agencies concerning the proposed collection of information 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 the information to be collected; and (4) Minimize the burden of the collection of information on those who are to respond; including the use of appropriate automated collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

This Notice also lists the following information:

*Title of Proposal:* Multifamily Coinurance Claims Package, Section 223(f).

*OMB Control Number:* 2505-0420.

*Description of the need for the information and proposed use:* Statute 12 U.S.C. 1715z-9 and Title II, Section 244 of the National Housing Act authorizes the Secretary of HUD to insure eligible multifamily mortgages against default. In the event of a default, the mortgagee is entitled to receive benefits under the coinsurance coverage prescribed in the provisions of 24 CFR Sections 255, 251.3, and 251.6. To receive these benefits the mortgagee must prepare and submit to HUD the appropriate forms. In addition, to comply with statutory requirements, the information collected is used by HUD to determine the claim amount due the mortgagee.

*Agency form number:* HUD-27008, 27009B, 27009D, 27009F.

*Estimation of the total numbers of hours needed to prepare the information collection including number of respondents, frequency of response, and hours of response:* The estimated number of respondents is 12, frequency of responses is one per claim submission, the total annual burden hours requested is 12.

*Status of the proposed information collection:* Reinstatement, with change, of a previously approved collection.

**Authority:** The Paperwork Reduction Act of 1995, 44 U.S.C. Chapter 35, as amended.

Dated: September 7, 2000.

**William C. Apgar,**

*Assistant Secretary for Housing-Federal Housing Commissioner.*

[FR Doc. 00-23522 Filed 9-12-00; 8:45 am]

**BILLING CODE 4210-27-M**

## DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR-4456-N-12]

### Privacy Act of 1974; Establishment of a New System of Records

**AGENCY:** Office of the Chief Information Officer, HUD.

**ACTION:** Notification of the Establishment of a New System of Records.

**SUMMARY:** Pursuant to the provisions of the Privacy Act of 1974 (5 U.S.C. 552a), as amended, the Department of Housing and Urban Development (HUD) is giving notice that it proposes to establish a new system of records entitled Independent Public Accountant Quality

Assurance Files which will be used in performing quality assurance reviews on the audited Financial Data Sheets and Automated Financial Submissions submitted to the Real Estate Assessment Center (REAC) either directly, or by the Independent Public Accountants (IPAs) of certain Public Housing Authorities (PHAs) and FHA-insured, direct loan, HUD-held or assisted multifamily property owners.

**DATES:** *Effective Date:* This proposal shall become effective without further notice on October 13, 2000, unless comments are received on or before that date which would result in a contrary determination.

*Comments Due By:* October 13, 2000.

**ADDRESSES:** Interested persons are invited to submit comments regarding this notice to the Rules Docket Clerk, Office of General Counsel, Room 10276, Department of Housing and Urban Development, 451 7th Street, SW., Washington, DC 20410-0500. Communications should refer to the above docket number and title. Comments submitted by facsimile (FAX) will not be accepted. A copy of each communication submitted will be available for public inspection and copying between 7:30 a.m. and 5:30 p.m. weekdays at the above address.

**FOR FURTHER INFORMATION CONTACT:** For Privacy Act information: Jeanette Smith, Departmental Privacy Act Officer, Telephone Number (202) 708-2374. For REAC, Financial Assessment Subsystem Quality Assurance information, Peter Bell, Director, Telephone Number (202) 708-4932, x3135. (These are not toll-free numbers). A telecommunications device for hearing and speech-impaired persons (TTY) is available at 1-800-877-8339 (Federal Information Relay Services). (This is a toll-free number).

**SUPPLEMENTARY INFORMATION:** Pursuant to the Privacy Act of 1974 (5 U.S.C. 552a), as amended, notice is given that HUD proposes to establish a new system of records identified as HUD/REAC-2, Independent Public Accountant Quality Assurance Files. REAC is responsible for evaluating the physical and financial condition of over 3,000 PHAs and over 30,000 Federal Housing Administration (FHA) multifamily insured, direct loan, HUD-held, and Section 8 project-based subsidized properties. To track the performance of these properties, certain PHAs are required to submit a Financial Data Sheet (FDS) and certain multifamily properties are required to submit an Automated Financial Submission (AFS) to REAC, which contains financial, audit, and compliance data. PHAs and multifamily property owners who are required to

submit an FDS or AFS are also required to have an independent audit performed by an independent public accountant. The IPA is then required to express an opinion as to the accuracy of the data contained on the FDS or AFS.

REAC performs a Quality Assurance Review (QAR) of the audited financial statements submitted by IPAs. This QAR provides HUD with the assurance that the information contained in the audited financial statements is accurate by independently reviewing the work of the IPAs performing the audits. The QAR process will also assure that the audits performed by these IPAs are being conducted in accordance with the auditing standards of the American Institute of Certified Public Accountants (AICPA) and government auditing standards issued by the General Accounting Office.

Title 5 U.S.C 552a(e)(4) and (11) provide that the public be afforded a 30-day period in which to comment on the new record systems. The new system report was submitted to the Office of Management and Budget (OMB), the Senate Committee on Governmental Affairs and the House Committee on Government Reform pursuant to paragraph 4c of Appendix 1 to OMB Circular No. A-130, "Federal Responsibilities for Maintaining Records About Individuals," July 25, 1994; 59 FR 37914.

Accordingly, this notice establishes a new system of records and accompanying routine uses to be created during the financial quality assurance review process at HUD's Real Estate Assessment Center.

**Authority:** 5 U.S.C. 552a:88 Stat. 1896; 342 U.S.C. 3535(d).

Dated: August 23, 2000.

**Susan K. Cooch,**

*Special Assistant, Office of Chief Information Officer.*

### HUD/REAC-2

#### SYSTEM NAME:

Independent Public Accountant Quality Assurance Files.

#### SYSTEM LOCATION:

Headquarters.

#### CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

All independent public accountants who have conducted audits of PHAs or FHA-insured, direct loan, HUD-held or assisted multifamily properties under HUD programs. An independent public accountant is defined as (a) a licensed, certified public accountant or a person working for a licensed certified public accounting firm, or (b) a public