

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on the draft guidance. 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 The draft guidance and received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.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 <http://www.fda.gov/ohrms/dockets/default.htm>, <http://www.fda.gov/cder/guidance/index.htm>, or <http://www.fda.gov/cber/reading.htm>.

Dated: August 29, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05-17597 Filed 9-2-05; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

Agency Information Collection Activities: Proposed Collection; Comment Request

ACTION: Notice and request for comments.

SUMMARY: The Federal Emergency Management Agency, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed information collections. In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3506(c)(2)(A)), this notice seeks comments concerning information required by FEMA to amend or revise National Flood Insurance Program Maps to remove certain property from the 1-percent annual chance floodplain.

SUPPLEMENTARY INFORMATION. With the passage of the Flood Disaster Protection Act of 1973, an owner of a structure, with a federally backed mortgage, located in the 1-percent annual chance floodplain, was required to purchase federal flood insurance. This was in response to the escalating damage caused by flooding and the unavailability of flood insurance from commercial insurance companies. As part of this effort, FEMA mapped the 1-percent annual chance floodplain in communities. However, due to scale limitations, individual structures that may be above the base flood cannot always be shown as being out of the 1-percent annual chance floodplain. FEMA will issue a Letter of Map Amendment (LOMA) or a Letter of Map Revision—Based on Fill (LOMR-F) to waive the Federal requirement for flood insurance when data is submitted to show that the property or structure is “reasonably safe from flooding” and at or above the elevation of the base flood.

Collection of Information

Title: Right to Submit Technical or Scientific Data to Correct Mapping Deficiencies.

Type of Information Collection: Revision of a Currently Approved Collection.

OMB Number: 1660-0015.

Form Numbers: FEMA Forms 81-87, 81-87A, 81-87B.

Abstract: The certification forms (referred to as MT-1 series forms) are designed to assist requesters in gathering information that FEMA needs to determine whether a certain property is likely to be flooded during the flood event that has a 1-percent annual chance of being equalled or exceeded in any given year (base flood). FEMA Form 81-87, Property Information, describes the location of the property, what is being requested, and what data are required to support the request. FEMA Form 81-87A, Elevation Information, indicates what the Base (1-percent annual chance) Flood Elevation (BFE) for the property is, how the BFE was determined, the lowest ground elevation on the property, and/or the elevation of the lowest adjacent grade to any structures on the property. This information is required in order for FEMA to determine if the property that the requester would like removed from the SFHA FEMA Form 81-87B, Community Acknowledgment, requires that a community official certify that the request complies with minimum floodplain management criteria specified in 44 CFR 60.3, as per NFIP regulations 44 CFR 65.5(a)(4).

Estimated Total Annual Burden Hours: 57,300.

ANNUAL BURDEN HOURS

| Project/activity (survey, form(s), focus group, etc.) | Number of respondents (A) | Frequency of responses (B) | Burden hours per respondent (C) | Annual responses (A × B) | Total annual burden hours (A × B × C) |
|---|---------------------------|----------------------------|---------------------------------|--------------------------|---------------------------------------|
| 81-87 | 18,272 | Annual (1) | 1.63 | 18,272 | 29,783 |
| 81-87A | 18,272 | Annual (1) | 1.25 | 18,272 | 22,840 |
| 81-87B | 3,389 | Annual (1) | 1.38 | 3,389 | 4,677 |
| Total | 39,933 | | 4.26 | 39,933 | 57,300 |

Estimated Cost. Cost to respondents is estimated to be \$1,325,597 annually, while the cost to the Federal Government is estimated to be \$94,300 annually.

Comments: Written comments are solicited to (a) evaluate whether the proposed data collection is necessary for the proper performance of the agency, including whether the information shall have practical utility; (b) evaluate the

accuracy of the agency’s estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (c) enhance the quality, utility, and clarity of the information to be collected; and (d) minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other

technological collection techniques or other forms of information technology, e.g., permitting electronic submissions of responses. Comments should be received within 60 days of the date of this notice.

ADDRESSES: Interested persons should submit written comments to Chief, Records Management Section, Information Resources Management Branch, Information Technology

Services Division, Federal Emergency Management Agency, Emergency Preparedness and Response Directorate, Department of Homeland Security, 500 C Street, SW., Room 316, Washington, DC 20472.

FOR FURTHER INFORMATION CONTACT: Contact Ms. Cecilia Lynch, FEMA, Federal Insurance and Mitigation Administration at (202) 646-7045 for additional information. You may contact the Records Management Section for copies of the proposed collection of information at facsimile number (202) 646-3347 or email address: *FEMA-Information-Collections@dhs.gov*.

Dated: August 26, 2005.

Deborah A. Moradi,

Acting Branch Chief, Information Resources Management Branch, Information Technology Services Division.

[FR Doc. 05-17627 Filed 9-2-05; 8:45 am]

BILLING CODE 9110-12-P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

Agency Information Collection Activities: Proposed Collection; Comment Request

ACTION: Notice and request for comments.

SUMMARY: The Federal Emergency Management Agency, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed information

collections. In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3506(c)(2)(A)), this notice seeks comments concerning information required by FEMA to revise National Flood Insurance Program Maps.

SUPPLEMENTARY INFORMATION: With the passage of the Flood Disaster Protection Act of 1973, an owner of a structure, with a federally backed mortgage, located in the 1-percent annual chance floodplain, was required to purchase federal flood insurance. This was in response to the escalating damage caused by flooding and the unavailability of flood insurance from commercial insurance companies. As part of this effort, FEMA mapped the 1-percent annual chance floodplain in communities. However, the 1-percent annual chance floodplain may change due to changes within the floodplain, or may be more accurately depicted through the use of more up-to-date methods and data. FEMA will issue a Letter of Map Revision to officially revise the 1-percent annual chance floodplain.

Collection of Information

Title: Consultation with Local Officials to Assure Compliance—Sec. 110 and 206.

Type of Information Collection. Revision of a currently approved collection.

OMB Number: 1660-0016.

Form Numbers. FEMA forms 81-89, 81-89A, 81-89B, 81-89C, 81-89D, 81-89E

Abstract. The certification forms (referred to as MT-2 series forms) are designed to assist requesters in gathering information that FEMA needs to revise a National Flood Insurance Program map.

FEMA Form 81-89, Overview and Concurrence Form, describes the location of the request, what is being requested, and what data are required to support the request. In addition, NFIP regulations 44 CFR 65.5(a)(4) require that a community official certify that the request complies with minimum floodplain management criteria specified in 44 CFR 60.3. This form ensures that this requirement is fulfilled prior to the submittal of the request to FEMA. FEMA Form 81-89A, Riverine Hydrology and Hydraulics Form, allows FEMA to efficiently review assumptions made, parameters used, and the results of hydrologic and hydraulic analyses performed in support of a revision request. It also addresses more common regulatory issues; FEMA Form 81-89B, Riverine Structures Form, allows FEMA to efficiently review assumptions made, parameters used, and the results of revision requests involving new or modified structures in riverine flood hazard areas; FEMA Form 81-89C, Coastal Analysis Form, allows FEMA to efficiently review assumptions made, parameters used, and the results of coastal analyses performed in support of a revision request. It also addresses more common regulatory issues; FEMA Form 81-89D, Coastal Structures Form, allows FEMA to efficiently review assumptions made, parameters used, and the results of revision requests involving new or modified structures in coastal flood hazard areas; FEMA Form 81-89E, Alluvial Fan Flooding Form, allows FEMA to efficiently review assumptions made, parameters used, and the results of alluvial fan flooding analyses performed in support of a revision request.

ESTIMATED TOTAL ANNUAL BURDEN HOURS

| FEMA forms | Number of respondents (A) | Frequency of response (B) | Hours per response (C) | Annual burden hours (A x B x C) |
|--------------|---------------------------|---------------------------|------------------------|---------------------------------|
| 81-89 | 1,400 | Annual | 1.0 | 1,400 |
| 81-89A | 1,400 | Annual | 3.5 | 4,320 |
| 81-89B | 1,400 | Annual | 7.0 | 10,080 |
| 81-89C | 1,400 | Annual | 1.0 | 1,400 |
| 81-89D | 1,400 | Annual | 1.0 | 1,400 |
| 81-89E | 1,400 | Annual | 1.0 | 1,400 |
| Total | 1,400 | | 14.5 | 20,880,000 |

Estimated Cost. Cost to respondents is estimated to be \$1,044,000 annually, while the cost to the Federal Government is estimated to be \$100,220 annually.

Comments: Written comments are solicited to (a) evaluate whether the

proposed data collection is necessary for the proper performance of the agency, including whether the information shall have practical utility; (b) evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of

the methodology and assumptions used; (c) enhance the quality, utility, and clarity of the information to be collected; and (d) minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated,