

notify the other party of any confirmed problem reports, corrective actions, or recalls.

These two draft guidance documents entitled "Implementation Plan for the Mutual Recognition Agreement Between the European Union and the United States of America: Confidence Building Programme: Overview" and "Implementation Plan for the Mutual Recognition Agreement Between the European Union and the United States of America: Procedures for Joint Confidence Building" provide guidance on how to implement confidence building activities under the Medical Device Annex of the MRA for quality system evaluations and product evaluations. Guidance on implementing an alert system will be issued separately at another time.

## II. Significance of Guidance

These draft guidance documents are intended to provide guidance. The draft guidance documents were developed by FDA and the European Commission (EC) to further implementation of the MRA. This current draft represents the EC's latest edits. FDA will be providing comments to the EC and proposing certain changes that are described in the "FDA Concerns" section of the guidance document. These draft guidance documents do not create or confer any rights for or on any person and do not operate to bind FDA or the public.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.

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). These guidance documents are issued as a draft Level 1 guidance consistent with GGP's.

## III. Electronic Access

Persons interested in obtaining copies of these draft guidance documents may do so through the Internet at [www.fda.gov/cdrh/mra](http://www.fda.gov/cdrh/mra).

## IV. Comments

Interested persons may submit to the Dockets Management Branch (address above) written comments regarding these draft guidance documents by November 2, 2000. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments should be identified with the

docket number found in brackets in the heading of this document. A copy of the draft guidance documents and received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday. To expedite receipt and review, FDA requests, if possible, that a copy of your comments be sent to the contact person (address above) or by e-mail to [mcn@cdrh.fda.gov](mailto:mcn@cdrh.fda.gov).

Dated: September 22, 2000.

**William K. Hubbard,**

*Senior Associate, Commissioner for Policy, Planning, and Legislation.*

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**BILLING CODE 4160-01-F**

## DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR-4563-N-16]

### Notice of Proposed Information Collection for Public Comment; Contract and Subcontract Activity

**AGENCY:** Office of the Assistant Secretary for Public and Indian 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 public comments on the subject proposal.

**DATES:** *Comments Due Date:* December 4, 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: Mildred M. Hamman, Reports Liaison Officer, Public and Indian Housing, Department of Housing and Urban Development, 451 7th Street, SW., Room 4238, Washington, DC 20410-5000.

**FOR FURTHER INFORMATION CONTACT:** Mildred M. Hamman, (202) 708-3642, extension 4128, for copies of the proposed forms and other available documents. (This is not a toll-free number).

**SUPPLEMENTARY INFORMATION:** The Department will submit 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 through 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:* Contract and Subcontract Activity.

*OMB Control Number:* 2577-0088.

*Description of the need for the information and proposed use:* The information provided to HUD by Housing Agencies/Grantees will be used to prepare an annual report on Minority Business Enterprise (MBE) participation in Public and Indian Housing Programs. The report will be submitted to the Department of Commerce pursuant to Executive Order 12432. HUD will also use the information to monitor and evaluate Housing Agency performance. HUD plans to collect this information electronically over the Internet.

*Agency form number:* HUD-2516.

*Members of affected public:* State, Local or Tribal Government, Small Businesses or Organizations.

*Estimation of the total number of hours needed to prepare the information collection including number of respondents, frequency of response, and hours of response:* 3,400 respondents annually, one hour per response, 3,400 total burden hours.

*Status of the proposed information collection:* Extension, without change.

**Authority:** Section 3506 of the Paperwork Reduction Act of 1995, 44 U.S.C. Chapter 35, as amended.

Dated: September 27, 2000.

**Milan Ozdinec,**

*General Deputy Assistant, Secretary for Public and Indian Housing.*

**BILLING CODE 4210-33-M**

Executive Order 12432 requires Federal agencies to promote Minority Business Enterprise (MBE) participation in their programs and prescribes additional arrangements for developing and coordinating a National Program for MBE. Pursuant to Executive Order 12432, the Department of Commerce requires an annual report on MBE achievements. The information provided on Public and Indian Housing Programs will be used to monitor and evaluate HA performance and to develop and submit the Annual Report to the President. Responses to the collection of information are voluntary. The information requested does not tend itself to confidentiality.

[illegible]

**7c: Type of Trade Codes:**

**Housing/Public Housing:** 6  
1 = New Construction 7  
2 = Substantial Rehab. 8  
3 = Repair 8  
4 = Service 9  
5 = Protect Managt 0

**CPD:**  
1 = New Construction  
2 = Education/Training  
3 = Other

**7d: Racial/Ethnic Codes:**  
 1 = White Americans  
 2 = Black Americans  
 3 = Native Americans  
 4 = Hispanic Americans  
 5 = Asian/Pacific Americans  
 6 = Hasidic Jews

**5: Program Codes** (Complete for Housing and Public and Indian Housing programs only):

1 = All Insured, including Section 8  
2 = Flexible Subsidy  
3 = Section 8 Noninsured, Non-HFDA  
4 = Insured Management  
5 = Section 202  
6 = HUD-Held (Management)  
7 = Public/Indian Housing

<p>This report is to be completed by grantees, developers, sponsors, builders, agencies, and/or project owners for reporting contract and subcontract activities of \$10,000 or more under the following programs: Community Development Block Grants (entitlement and special funds); Urban Development Action Grants; Housing Development Grants; Multifamily Insured and Noninsured; Public and Indian Housing Authorities; and contracts entered into by recipients of CDBG rehabilitation assistance.</p> <p>Contract/subcontract activities of less than \$10,000 need be reported only if such contracts represent a significant portion of your total contracting activity. Include only contracts executed during this reporting period.</p> <p>This form has been modified to capture Section 3 contract data in columns 7g and 7i. Section 3 requires that the employment and other economic opportunities generated by HUD financial assistance for housing and community development programs shall, to the greatest extent feasible, be directed toward low- and very low-income persons, particularly those who are recipients of government assistance for housing. Recipients using this form to report Section 3 contract data must also use Part I of form HUD-60502 to report employment and training opportunities data. Form HUD-2516 is to be completed</p>	<p>for public and Indian housing and most community development programs. Form HUD-60502 is to be completed by all other HUD programs including State administered community development programs covered under Section 3.</p> <p>A Section 3 contractor/subcontractor is a business concern that provides economic opportunities to low- and very low-income residents of the metropolitan area (or nonmetropolitan county), including a business concern that is 51 percent or more owned by low- or very low-income residents, employs a substantial number of low- or very low-income residents, or provides subcontracting or business development opportunities to businesses owned by low- or very low-income residents. Low- and very low-income residents include participants in Youthbuild programs established under Subtitle C of Title IV of the Cranston-Carter National Affordable Housing Act.</p> <p>The terms "low-income persons" and "very low-income persons" have the same meanings given the terms in section 3(b)(2) of the United States Housing Act of 1937. Low-income persons mean families (including single persons) whose incomes do not exceed 80 percent of the median income for the area, as determined by the Secretary, with adjustments for smaller and larger families, except that the Secretary may establish</p>	<p>income ceilings higher or lower than 80 percent of the median for the area on the basis of the Secretary's findings that such variations are necessary because of prevailing levels of construction costs or unusually high or low income levels. Very low-income persons mean low-income families (including single persons) whose incomes do not exceed 50 percent of the median family income for the area, as determined by the Secretary with adjustments for smaller and larger families, except that the Secretary may establish income ceilings higher or lower than 50 percent of the median for the area on the basis of the Secretary's findings that such variations are necessary because of unusually high or low family incomes.</p> <p>Submit two (2) copies of this report to your local HUD Office within ten (10) days after the end of the reporting period you checked in item 4 on the front.</p> <p>Complete item 7h, only once for each contract/subcontract on each semi-annual report.</p> <p>Enter the prime contractor's ID in item 7i for all contracts and subcontracts. Include only contracts executed during this reporting period. <i>Prime/PMs are to report all contract/subcontracts.</i></p>	<p>Form HUD-2516 (3-96)</p>
<p><b>Community Development Programs</b></p> <p>1. <b>Grantee:</b> Enter the name of the unit of government submitting this report.</p> <p>2. <b>Contact Person:</b> Enter name and phone of person responsible for maintaining and submitting contract/subcontract data.</p> <p>7a. <b>Grant Number:</b> Enter the HUD Community Development Block Grant Identification Number (with dashes). For example: D-32-MC-22-0034. For Entitlement Programs and Small City multi-year contracts, enter the latest approved grant number.</p> <p>7b. <b>Amount of Contract/Subcontract:</b> Enter the dollar amount rounded to the nearest dollar. If subcontractor ID number is provided in 7i, the dollar figure would be for the subcontract only and not for the prime contract.</p> <p>7c. <b>Type of Trade:</b> Enter the number code which best indicates the contractor's subcontractor's service. If subcontractor ID number is provided in 7i, the type of trade code would be for the subcontractor only and not for the prime contractor. The "other" category includes supply, professional services and all other activities except construction and education/training activities.</p> <p>7d. <b>Business Racial/Ethnic/Gender Code:</b> Enter the number code which indicates the racial/ethnic gender character of the contract(s) and contract(s) of 51% of the business. When 51% or more is not owned and controlled by any single racial/ethnic gender category, enter the code which seems most appropriate. If the subcontractor ID number is provided, the code would apply to the subcontractor and not to the prime contractor.</p> <p>7e. <b>Women Owned Business:</b> Enter Yes or No.</p> <p>7f. <b>Contractor Identification (ID) Number:</b> Enter the Employer (PIS) Number of the Prime Contractor as the unique identifier for prime recipient of HUD funds. Note that the Employer (PIS) Number must be provided for each contract/subcontract awarded.</p> <p>7g. <b>Section 3 Contractor:</b> Enter Yes or No.</p> <p>7h. <b>Subcontractor Identification (ID) Number:</b> Enter the Employer (PIS) Number of the subcontractor as the unique identifier for each subcontract awarded from HUD funds. When the subcontractor ID Number is provided, the respective Prime Contractor ID Number must also be provided.</p> <p>7i. <b>Section 3 Contractor:</b> Enter Yes or No.</p> <p>7j. <b>Contractor/Subcontractor Name and Address:</b> Enter this information for each firm receiving contract/subcontract activity only one time on each report for each firm. Previous editions are obsolete.</p>	<p><b>Multifamily Housing Programs</b></p> <p>1. <b>Grantee/Project Owner:</b> Enter the name of the unit of government, agency or manager entity submitting this report.</p> <p>3. <b>Contact Person:</b> Same as item 3 under CDP Programs.</p> <p>4. <b>Reporting Period:</b> Check only one period.</p> <p>5. <b>Program Code:</b> Enter the appropriate program code.</p> <p>7a. <b>Grant/Project Number:</b> Enter the HUD Project Number or Housing Development Grant or number assigned.</p> <p>7b. <b>Amount of Contract/Subcontract:</b> Same as item 7b under CDP Programs.</p> <p>7c. <b>Type of Trade:</b> Same as item 7c under CDP Programs.</p> <p>7d. <b>Business Racial/Ethnic/Gender Code:</b> Same as item 7d under CDP Programs.</p> <p>7e. <b>Women Owned Business:</b> Enter Yes or No.</p> <p>7f. <b>Contractor Identification (ID) Number:</b> Same as item 7f under CDP Programs.</p> <p>7g. <b>Section 3 Contractor:</b> Enter Yes or No.</p> <p>7h. <b>Subcontractor Identification (ID) Number:</b> Same as item 7h under CDP Programs.</p> <p>7i. <b>Section 3 Contractor:</b> Enter Yes or No.</p> <p>7j. <b>Contractor/Subcontractor Name and Address:</b> Same as item 7j under CDP Programs.</p>	<p><b>Public Housing and Indian Housing Programs</b></p> <p>1. <b>Project Owner:</b> Enter the name of the unit of government, agency or manager entity submitting this report. Check box as appropriate.</p> <p>3. <b>Contact Person:</b> Same as item 3 under CDP Programs.</p> <p>4. <b>Reporting Period:</b> Check only one period.</p> <p>5. <b>Program Code:</b> Enter the appropriate program code.</p> <p>7a. <b>Grant/Project Number:</b> Enter the HUD Project Number or Housing Development Grant or number assigned.</p> <p>7b. <b>Amount of Contract/Subcontract:</b> Same as item 7b under CDP Programs.</p> <p>7c. <b>Type of Trade:</b> Same as item 7c under CDP Programs.</p> <p>7d. <b>Business Racial/Ethnic/Gender Code:</b> Same as item 7d under CDP Programs.</p> <p>7e. <b>Women Owned Business:</b> Enter Yes or No.</p> <p>7f. <b>Contractor Identification (ID) Number:</b> Same as item 7f under CDP Programs.</p> <p>7g. <b>Section 3 Contractor:</b> Enter Yes or No.</p> <p>7h. <b>Subcontractor Identification (ID) Number:</b> Same as item 7h under CDP Programs.</p> <p>7i. <b>Section 3 Contractor:</b> Enter Yes or No.</p> <p>7j. <b>Contractor/Subcontractor Name and Address:</b> Same as item 7j under CDP Programs.</p>	<p>Form HUD-2516 (3-96)</p>