

regulation, by publishing the OMB control number in the preamble or the regulatory text for the final rule, in a technical amendment to the final rule, or in a separate notice announcing OMB approval of the collection of information) and/or in the Code of Federal Regulations. For ease of future reference, OMB recommends that, even where an agency has already "displayed" the OMB control number by publishing it in the **Federal Register**, the agency also publish the currently valid OMB control number in the Code of Federal Regulations.

(4) In other cases, and where OMB determines in advance in writing that special circumstances exist, to use other means to inform potential respondents of the OMB control number.

(g) *Independent regulatory agency* means the Board of Governors of the Federal Reserve System, the Commodity Futures Trading Commission, the Consumer Product Safety Commission, the Federal Communications Commission, the Federal Deposit Insurance Corporation, the Federal Energy Regulatory Commission, the Federal Housing Finance Board, the Federal Maritime Commission, the Federal Trade Commission, the Interstate Commerce Commission, the Mine Enforcement Safety and Health Commission, the National Labor Relations Board, the Nuclear Regulatory Commission, the Occupational Safety and Health Review Commission, the Postal Rate Commission, the Securities and Exchange Commission, and any other similar agency designated by statute as a Federal independent regulatory agency or commission.

(h) *Information* means any statement of fact or opinion, regardless of form or format, whether in numerical, graphic, or narrative form, and whether oral or maintained on paper, electronic or other media. "Information" does not generally include items in the following categories; however, OMB may determine that any specific item constitutes "information":

(1) Affidavits, oaths, affirmations, certifications, receipts, changes of address, consents, or acknowledgments; provided that they entail no burden other than that necessary to identify the respondent, the date, the respondent's address, and the nature of the instrument (by contrast, a certification would likely involve the collection of "information" if an agency conducted or sponsored it as a substitute for a collection of information to collect evidence of, or to monitor, compliance with regulatory standards, because such a certification would generally entail burden in addition to that necessary to

identify the respondent, the date, the respondent's address, and the nature of the instrument);

(2) Samples of products or of any other physical objects;

(3) Facts or opinions obtained through direct observation by an employee or agency of the sponsoring agency or through nonstandardized oral communication in connection with such direct observations;

(4) Facts or opinions submitted in response to general solicitations of comments from the public, published in the **Federal Register** or other publications, regardless of the form or format thereof, provided that no person is required to supply specific information pertaining to the commenter, other than that necessary for self-identification, as a condition of the agency's full consideration of the comment;

(5) Facts or opinions obtained initially or in follow-on requests, from individuals (including individuals in control groups) under treatment or clinical examination in connection with research on or prophylaxis to prevent a clinical disorder, direct treatment of that disorder, or the interpretation of biological analyses of body fluids, tissues, or other specimens, or the identification or classification of such specimens;

(6) A request for facts or opinions addressed to a single person;

(7) Examinations designed to test the aptitude, abilities, or knowledge of the persons tested and the collection of information for identification or classification in connection with such examinations;

(8) Facts or opinions obtained or solicited at or in connection with public hearings or meetings;

(9) Facts or opinions obtained or solicited through nonstandardized follow-up questions designed to clarify responses to approved collections of information; and

(10) Like items so designated by OMB.

(i) OMB refers to the Office of Management and Budget.

(j) Penalty includes the imposition by an agency or court of a fine or other punishment; a judgment for monetary damages or equitable relief; or the revocation, suspension, reduction, or denial of a license, privilege, right, grant, or benefit.

(k) Person means an individual, partnership, association, corporation (including operations of government-owned contractor-operated facilities), business trust, or legal representative, an organized group of individuals, a State, territorial, tribal, or local government or branch thereof, or a

political subdivision of a State, territory, tribal, or local government or a branch of a political subdivision;

(l) Practical utility means the actual, not merely the theoretical or potential, usefulness of information to or for an agency, taking into account its accuracy, adequacy, and reliability, and the agency's ability to process the information it collects (or the public's ability to process the information it receives, in the case of a third-party or public disclosure) in a useful and timely fashion. In determining whether information will have "practical utility," OMB will take into account whether the agency demonstrates actual timely use for the information either to carry out its functions or make it available to third-parties or the public, either directly or by means of a third-party or public posting, notification, labeling, or similar disclosure requirement, for the use of persons who have an interest in entities or transactions over which the agency has jurisdiction. In the case of recordkeeping or general purpose statistics, which are those statistics collected chiefly for public and general government uses and without primary reference to policy or program operations of the agency collecting the information, "practical utility" means that actual uses can be demonstrated.

(m) Recordkeeping requirement means a requirement imposed by or for an agency on persons to maintain specified records, including a requirement to:

(1) Retain such records;

(2) Notify third parties, the Federal government, or the public of the existence of such records;

(3) Disclose such records to third parties, the Federal government, or the public; or

(4) Report to third parties, the Federal government, or the public regarding such records.

#### § 1320.4 Coverage.

(a) The requirements of this Part apply to all agencies as defined in § 1320.3(a) and to all collections of information conducted or sponsored by those agencies, as defined in § 1320.3(c) and (d), wherever conducted or sponsored, but, except as provided in paragraph (b) of this section, shall not apply to collections of information:

(1) During the conduct of a Federal criminal investigation or prosecution, or during the disposition of a particular criminal matter;

(2) During the conduct of a civil action to which the United States or any official or agency thereof is a part, or during the conduct of an administrative