guidance documents on quality systems auditing practices. As a result of its efforts, this group has developed document SG4(PD)N33R13:2006. SG4(PD)N33R13:2006 (proposed document), entitled ''Guidelines for Regulatory Auditing of Quality Management Systems of Medical Device Manufacturers—Part 3: Regulatory Audit Reports,'' suggests a structure for audit reports used in multiple jurisdictions, promoting consistency and uniformity and should assist the auditor in preparing a report for use by multiple regulators and/or auditing organizations. Having reports that are consistent in content should facilitate the review and exchange of audit reports. Acceptance of audit reports by multiple regulators should eventually reduce the number of audits for manufacturers.

Study Group 2 was initially tasked with the responsibility of developing guidance documents that will be used for the exchange of adverse event reports. As a result of its efforts, this group developed SG2N54R8:2006. SG2N54R8:2006 (final document), entitled ''Medical Devices Post Market Surveillance: Global Guidance for Adverse Event Reporting for Medical Devices,'' provides guidance on the type of adverse events associated with medical devices that should be reported by manufacturers to a National Competent Authority. It elaborates on the regulatory requirements existing in the participating member countries.

II. Significance of Guidance

These documents represent recommendations from the GHTF study groups and do not describe regulatory requirements. FDA is making these documents available so that industry and other members of the public may express their views and opinions.

III. Electronic Access

Persons interested in obtaining a copy of the documents may also do so by using the Internet. The Center for Devices and Radiological Health (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 Internet access. Updated on a regular basis, the CDRH home page includes device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturer's assistance, information on video conferencing and electronic submissions, Mammography Matters, and other device-oriented information. Information on the GHTF may be accessed at *http://www.ghtf.org*. The CDRH web site may be accessed at *http://www.fda.gov/cdrh*.

IV. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**), written or electronic comments regarding these documents. 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. Comments received may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: January 30, 2007.

Linda S. Kahan,

Deputy Director, Center for Devices and Radiological Health.

[FR Doc. E7–1864 Filed 2–5–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection Comment Request

In compliance with the requirement for opportunity for public comment on proposed data collection projects (section 3506(c)(2) of Title 44, United States Code, as amended by the Paperwork Reduction Act of 1995, Public Law 104–13), the Health Resources and Services Administration (HRSA) will publish periodic summaries of proposed projects being developed for submission to the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995. To request more information on the proposed project or to obtain a copy of the data collection plans, call the HRSA Reports Clearance Officer on (301) 443–1129.

Comments are invited 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) ways to enhance 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.

Proposed Project: Reporting Form for the MCHB National Hemophilia Program Grantees and Hemophilia Treatment Center (HTC) Affiliates Having Factor Replacement Product (FRP) Programs—NEW

The Maternal and Child Health Bureau (MCHB) of the Health Resources and Services Administration (HRSA) is planning to implement an annual reporting form required of grantees of the MCHB National Hemophilia Program and their HTC affiliates having a factor replacement product (FRP) program. The purpose of the form is to provide systematic information and data comprising a financial overview of the FRP programs of the HTCs receiving funding through grantees of the MCHB National Hemophilia Program. The proposed form will constitute a reporting requirement for the MCHB National Hemophilia Program grantees and their affiliate HTCs having FRP programs.

Data from the form will provide quantitative information on the financial and services provision aspects of each of the HTC FRP programs under each of the MCHB National Hemophilia Program grantees, specifically: (a) Patient FRP program participation, (b) FRP program revenue, (c) FRP program costs, (d) FRP program net income, and (e) use of FRP program net income. This form will provide data useful to grantees and their affiliate HTCs having FRP programs. Useful data will also be provided to the MCHB National Hemophilia Program in order to assess FRP program performance including FRP program operational costs appropriateness, FRP program cost efficiency, and FRP program services benefits-information that is essential to evaluating HTCs having FRP programs, grantees, and the MCHB National Hemophilia Program.

Each HTC having an FRP program is to submit its report to the grantee and each grantee is to submit the individual reports of each of their affiliate HTCs having an FRP program to the MCHB National Hemophilia Program as a part of their annual grant application.

The burden estimate for this project is as follows:

Form	Number of respondents	Average number of responses per respondent	Total responses	Hours per response	Total burden hours
Factor Replacement Product (FRP) Data Sheet	68	1	68	30	2040

Send comments to Susan G. Queen, Ph.D., HRSA Reports Clearance Officer, Room 10–33 Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857. Written comments should be received within 60 days of this notice.

Dated: January 29, 2007.

Caroline Lewis,

Acting Associate Administrator for Administration and Financial Management.

[FR Doc. E7–1824 Filed 2–5–07; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Comment Request

In compliance with the requirement for opportunity for public comment on proposed data collection projects (section 3506(c)(2)(A) of Title 44, United States Code, as amended by the Paperwork Reduction Act of 1995, Public Law 104–13), the Health Resources and Services Administration (HRSA) publishes periodic summaries of proposed projects being developed for submission to the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995. To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, call the HRSA Reports Clearance Officer on (301) 443–1129.

Comments are invited 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) ways to enhance 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.

Proposed Project: ''Health Care and Other Facilities'' Construction Program: Web-Based Status Reporting Form: NEW

The Health Resources and Services Administration's Health Care and Other Facilities (HCOF) construction program provides earmarked funds to health-related facilities for construction-related activities and/or capital equipment purchases. Awarded facilities are required to provide a periodic (quarterly for construction-related projects, annually for equipment only projects) update of the status of the funded project until it is completed. The monitoring period averages about 3 years, although some projects take up to 5 years to complete. The information collected from these updates is vital to program management staff to determine whether projects are progressing according to the established timeframes, meeting deadlines established in the Notice of Grant Award (NGA), and funds are drawn down appropriately. The data collected from the updates is also shared with both the Division of Grants Management Operations (DGMO) and the Division of Engineering Services (DES), so that they can assist in the overall evaluation of each project's progress.

A Web-based form has been developed for progress reporting for the HCOF program. This form will provide awardees access to directly input the required status update information in a timely, consistent, and uniform manner. The Web-based form will minimize burden to respondents and will inform respondents when there are missing data elements prior to submission.

The estimate of burden for the forms is as follows:

Project type (current)	Number of respondents	Responses per respondent	Total responses	Hours per response	Total burden hours
Construction-Related	325	4	1,300	.5	650
Equipment Only	357	1	357	.5	178.5
Total	682	.....	1,657	.....	828.5

Project type (FY 07–09 projection)	Number of respondents	Responses per espondent	Total responses	Hours per response	Total burden hours
Construction-Related*	498	4	1,992	.5	996
Equipment Only**	925	1	925	.5	462.5
Total	1,423	.....	2,917	.....	1,458