use, maintain and store a device; residual risks; warnings and contraindications. This document applies to all products that fall within the definition of a medical device that appears within the GHTF document SG1/N29:2005 entitled ''Information Document Concerning the Definition of the Term 'Medical Device,''' including those used for the in vitro examination of specimens derived from the human body. The new guidance is intended to supersede the previous version of the guidance.

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 has developed proposed documents SG2(PD)/N54R6:2005, SG2(PD)/N57R6:2005, and SG2(PD)/N79R5:2005 and final document SG2/N38R14:2005.

SG2/(PD)/N54R6:2005 (proposed document) entitled ''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 (NCA). SG2(PD)/N57R6:2005 (proposed document) entitled ''Medical Devices: Post Market Surveillance: Content of Field Safety Notices'' identifies elements that should be included in safety related notifications issued by the medical device manufacturer. SG2/(PD)/N79R5:2005 (proposed document) entitled ''Medical Devices: Post Market Surveillance: National Competent Authority Report Exchange Criteria and Report Form'' provides guidance, procedures, and forms for the exchange of reports concerning the safety of medical devices between NCA and other participants of the GHTF National Competent Authority Report (NCAR) exchange program.

SG2/N38R15:2005 (final document) entitled ''Application Requirements for Participation in the GHTF National Competent Authority Report Exchange Program'' describes the prerequisites and commitments required from an organization before it can participate in the NCAR exchange program founded by GHTF SG2.

Study Group 3 was initially tasked with the responsibility of developing guidance documents on quality systems. As a result of its efforts, this group has developed final document SG3/N15R8:2005. SG3/N15R8:2005 (final document) entitled ''Implementation of Risk Management Principles and Activities within a Quality Management System'' is intended to assist medical device manufacturers with the integration of a risk management system or risk management principles and activities into their existing quality management system by providing practical explanations and examples. This document assumes a basic understanding of quality management system requirements and a basic knowledge of quality management system terminology.

Study Group 4 was initially tasked with the responsibility of developing guidance documents on quality systems auditing practices. As a result of its efforts, this group has developed document SG4(PD)/N30R16:2005. SG4(PD)/N30R16:2005 (proposed document) entitled ''Guidelines for Regulatory Auditing of Quality Management Systems of Medical Device Manufacturers—Part 2: Regulatory Auditing Strategy'' is intended to assist medical device regulators and auditing organizations conducting quality management system audits of medical device manufacturers based on the process approach to quality management system requirements (e.g., ISO 13485:2003 and 21 CFR Part 820).

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 guidances 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 17, 2006.

Linda S. Kahan,

Deputy Director, Center for Devices and Radiological Health.

[FR Doc. E6–846 Filed 1–24–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Health Resources and Services Administration (HRSA) publishes abstracts of information collection requests under review by the Office of Management and Budget (OMB), in compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35). To request a copy of the clearance requests submitted to OMB for review, call the HRSA Reports Clearance Office on (301)–443–1129.

The following request has been submitted to the Office of Management and Budget for review under the Paperwork Reduction Act of 1995:

Proposed Project: Maternal and Child Health Bureau Performance Measures for Discretionary Grants (OMB No. 0915–0272)

The Maternal and Child Health Bureau (MCHB) intends to continue to collect performance data for Special Projects of Regional and National Significance (SPRANS), Community Integrated Service Systems (CISS), and other grant programs administered by MCHB.

The Health Resources and Services Administration (HRSA) proposes to continue using reporting requirements for SPRANS projects, CISS projects, and other grant programs administered by MCHB, including national performance measures, previously approved by OMB, and in accordance with the ''Government Performance and Results Act (GPRA) of 1993'' (Pub. L. 103–62). This Act requires the establishment of

measurable goals for Federal Programs that can be reported as part of the budgetary process, thus linking funding decisions with performance. Performance measures for MCHB discretionary grants were initially approved in January 2003. Approval from OMB is being sought to continue the use of these measures. The number of measures has been reduced with the transfer of a program to the Administration for Children and Families. The remaining performance measures are unchanged from those approved in 2003. Some of these measures are specific to certain types of programs, and will not apply to all grantees. Furthermore, these measures are based primarily on existing data, thereby minimizing the response burden consistent with program administration and management needs.

The estimated response burden is as follows:

Form	Number of respondents	Responses per respondent	Total responses	Burden per response	Total burden hours
Grant Report	631	1	631	6	3,786

Written comments and recommendations concerning the proposed information collection should be sent within 30 days of this notice to: John Kraemer, Human Resources and Housing Branch, Office of Management and Budget, New Executive Office Building, Room 10235, Washington, DC 20503.

Dated: January 19, 2006.

Tina M. Cheatham,

Director, Division of Policy Review and Coordination.

[FR Doc. E6–893 Filed 1–24–06; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Health Resources and Services Administration (HRSA) publishes abstracts of information collection requests under review by the Office of Management and Budget (OMB), in compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35). To request a copy of the clearance requests submitted to OMB for review, call the HRSA Reports Clearance Office on (301) 443–1129.

The following request has been submitted to the Office of Management and Budget for review under the Paperwork Reduction Act of 1995:

Proposed Project: The Health Professions Student Loan (HPSL) and Nursing Student Loan (NSL) Programs: Forms (OMB No. 0915–0044): Extension

The HPSL Program Provides long-term, low-interest loans to students attending schools of medicine, osteopathic medicine, dentistry, veterinary medicine, optometry, podiatric medicine, and pharmacy. The NSL Program provides long-term, low-interest loans to students who attend eligible schools of nursing in programs leading to a diploma in nursing, and an associate degree, a baccalaureate degree, or a graduate degree in nursing. Participating HPSL and NSL schools are responsible for determining eligibility of applicants, making loans, and collecting monies owed by borrowers on their outstanding loans. The deferment form (HRSA form 519) provides the schools with documentation of a borrower's eligibility for deferment. The Annual Operating Report (AORHRSA form 501) provides the Federal Government with information from participating and non-participating schools (schools that are no longer granting loans but are required to report and maintain program records, student records, and repayment records until all student loans are repaid in full and all monies due the Federal Government are returned) relating to HPSL and NSL program operations and financial activities.

The estimate of burden is as follows:

Form	Number of respondents	Responses per respondent	Total responses	Hours per responses	Total burden hours
Deferment HRSA–519	3,000	1	3,000	[1] 10	500
AOR–HRSA–501	977	1	977	[2] 4	3,908
Total Burden	3,977		3,977		4,408

[1] Minutes.
[2] Hours.

Written comments and recommendations concerning the proposed information collection should be sent within 30 days of this notice to: John Kraemer, Human Resources and Housing Branch, Office of Management and Budget, New Executive Office Building, Room 10235, Washington, DC 20503.

Dated: January 19, 2006.

Tina M. Cheatham,

Director, Division of Policy Review and Coordination.

[FR Doc. E6–894 Filed 1–24–06; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; Comment Request

A Survey of Estimated Glomerular Filtration Rate (GFR) Reporting Practices of Clinical Laboratories.

Summary: In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995,