instance of potential health-endangering spoilage, process deviation, or contamination with microorganisms where any lot of the food has entered distribution in commerce (§§ 108.25(d) and 108.35(d) and (e)); and to develop and keep on file plans for recalling products that may endanger the public health (§§ 108.25(e) and 108.35(f)). To permit lots to be traced after distribution, acidified foods and thermally processed low-acid foods in hermetically sealed containers must be marked with an identifying code (§§ 113.60(c) (thermally processed foods) and 114.80(b) (acidified foods)).

In the **Federal Register** of February 7, 2005 (70 FR 6445), FDA published a 60-day notice requesting public comment on the information collection provisions. No comments were received.

FDA estimates the burden of the collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

Form No.	21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
FDA 2541 (registration)	108.25 and 108.35	585	1	585	0.17	99
FDA 2541a (process filing)	108.25 and 108.35	1,778	9	16,002	0.333	5,329
FDA 2541(c)	108.35	124	10	1,240	0.75	930
Total						6,358

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 CFR Part	No. of Recordkeepers	Annual Frequency per Record	Total Annual Records	Hours per Recordkeeper	Total Hours
Parts 113 and 114	7,915	1	7,915	250	1,978,750

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

The reporting burden for §§ 108.25(d) and 108.35(d) and (e) is insignificant because notification of spoilage, process deviation, or contamination of product in distribution occurs less than once a year. Most firms discover these problems before the product is distributed and, therefore, are not required to report the occurrence. To avoid double-counting, estimates for §§ 108.25(g) and 108.35(h) have not been included because they merely cross reference recordkeeping requirements contained in parts 113 and 114.

There are approximately 7,915 food processing establishments, both foreign and domestic, registered as processors of acidified foods or thermally processed low-acid foods in hermetically sealed containers. Four FDA staff persons who are experienced in actual food processing plant operations and familiar with the regulations reviewed the recordkeeping procedures used by the industry.

Standardized timeframe requirements for conducting the recordkeeping procedures do not exist but it is estimated to take 250 hours per establishment to comply with the recordkeeping requirements in parts 108, 113, and 114. This compares satisfactorily when based upon firsthand food processing plant experience, individual estimates of the timeframes, and the frequency of recordkeeping.

Dated: April 1, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–7028 Filed 4–7–05; 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)(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 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 at (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: Division of Perinatal Systems and Women's Health—Forms for the Guidance for Healthy Start Program Application and Other Reports—New

The Application Guidance for grants within the Division of Healthy Start and Perinatal Services (DHSPS) is used annually by all community based Healthy Start organizations and agencies applying for funding (either continued or new), and in preparing the required annual report. The guidance provides guidelines to the organizations and agencies on how to apply for Healthy Start funds. Included in the guidance are a number of data collection forms, which are used annually by organizations that have applied for and/

or are receiving Healthy Start funding. It is proposed that additional data be collected and reported to provide increased program information. The completion of the new and existing forms by all applicants has an estimated overall burden of 500 hours, or approximately five (5) hours per respondent. The burden estimate for this activity is based upon information provided by current and past funded Healthy Start grantees, as well as previous experience in completing the current forms.

The estimated response burden is as follows:

Application and annual report	Estimated number of respondents	Responses per respondent	Burden hours per response	Total burden hours
Community Based Organizations and Agencies	100	1	5	500

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

Dated: April 1, 2005.

Tina M. Cheatham,

Director, Division of Policy Review and Coordination.

[FR Doc. 05–7018 Filed 4–7–05; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

HHS Approval of Professional Organizations and States' Standards for Certification

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Solicitation of comments.

SUMMARY: The Health Resources and Services Administration's (HRSA) Healthcare Systems Bureau, Division of Healthcare Preparedness Poison Control Program, provides supplemental funding to Poison Control Centers (PCCs) across the United States, promotes universal access to PCC services, and encourages the enhancement and improvement of poison education, prevention, and treatment. To receive funding from HRSA, PCCs must meet certain certification requirements. The purpose of this solicitation of comments is to assist HRSA in establishing criteria/guidelines to approve professional organizations and State governments' certification standards for PCCs.

DATES: To be considered, written comments should be postmarked no later than June 7, 2005.

ADDRESSES: Please send all comments to HRSA's Division of Healthcare Preparedness, Healthcare Systems Bureau, Attention: Maxine Jones, Room 13–103, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Maxine Jones, HRSA, HSB, Division of Healthcare Preparedness, (301) 443–6192, fax (301) 443–4922, or e-mail *mjones@hrsa.gov*.

SUPPLEMENTARY INFORMATION:

Background

In February 2000, Congress enacted the Poison Control Center Enhancement and Awareness Act, Pub. L. No. 106–174. This Act authorized funding to establish a national toll-free number to access Poison Control Center (PCC) services, a nationwide poison prevention media campaign, and a grant program to achieve financial stability of PCCs. In addition, the Act directed the Secretary of HHS to: (1) Develop standard education programs; (2) develop standard patient management protocols for commonly encountered exposures; (3) improve and expand the poison control data collection systems; (4) improve national toxic exposure surveillance, and (5) expand the physician/medical toxicologist supervision of PCCs. This Act was amended by Public Law 108–194, the Poison Control Enhancement and Awareness Act Amendments of 2003, which directs the Secretary of HHS to improve the capacity of poison control centers to answer high volumes of calls during times of national crisis, in addition to the activities listed in the original Act.

The grant program that was established provides funding for financial stabilization, certification, and incentive grants. Financial stabilization grants assist with financial stabilization and the improvement of services in PCCs that already meet American Association of Poison Control Centers (AAPCC) certification standards. Certification grants assist uncertified centers in efforts to attain certification status in addition to promoting enhancement of services. Incentive grants are awarded to PCCs that are working collaboratively and innovatively to improve poison control systems and services.

In general, PCCs must meet the certification requirements listed in Public Law 108–194 sec. 1273(c) to receive funding from HRSA. One way PCCs can fulfill this requirement is if the PCC ''has been certified by a professional organization in the field of poison control, and the Secretary has approved the organization as having in effect standards for certification that reasonably provide for the protection of the public health with respect to poisoning.'' The second way PCCs can fulfill this requirement is if the PCC ''has been certified by a State government, and the Secretary has approved the State government as having in effect standards for certification that reasonably provide for the protection of the public health with respect to poisoning.'' (Pub. L. No. 108–194 sec. 1273(c)).

Solicitation of Comments

The HRSA is seeking public input regarding guidelines by which the Secretary shall approve professional organizations and State governments as having in effect standards for PCC certification. Respondents are asked to submit recommended guidelines for approving professional organizations and State governments' standards for certification, per Public Law 108–194 sec. 1273(c).

Written comments should be limited to no more than 10 double-spaced pages or 5 single-spaced pages and should contain the name, address, telephone, and fax numbers, and any organizational affiliation of the persons providing written comments. Respondents may be contacted by the Poison Control Program, HRSA, to answer questions regarding their submitted comments. We are particularly interested in comments which address but are not limited to the following issues:

1. Modeling the guidelines after certification requirements that are currently being used to certify PCCs;