Dated: February 1, 2006.

Betsey Dunaway,

Acting Reports Clearance Officer, Centers for Disease Control and Prevention.

[FR Doc. E6–1692 Filed 2–7–06; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day–06–0576]

Agency Forms Undergoing Paperwork Reduction Act Review

The Centers for Disease Control and Prevention (CDC) publishes a list of information collection requests under review by the Office of Management and Budget (OMB) in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these requests, call the CDC Reports Clearance Officer at (404) 639–4766 or send an e-mail to *omb@cdc.gov.* Send written comments to CDC Desk Officer, Office of Management and Budget, Washington, DC or by fax to (202) 395–6974. Written comments should be received within 30 days of this notice.

Proposed Project

Possession, Use, and Transfer of Select Agents and Toxins (OMB Control No. 0920–0576)—Revision—Office of the Director (OD), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Pub. L. 107–188) specifies that the Secretary of Health and Human Services (HHS) shall provide for the establishment and enforcement of standards and procedures governing the possession, use, and transfer of select agents and toxins that have the potential to pose a severe threat to public health and safety. The Act specifies that entities that possess, use, and transfer these select agents register with the HHS Secretary. The HHS Secretary has designated CDC as the agency responsible for collecting this information.

CDC is requesting continued OMB approval to collect this information through the use of five separate forms. These forms are: (1) Application for Registration, (2) Request to Transfer Select Agent or Toxin, (3) Report of Theft, Loss, or Release of Select Agent and Toxin, (4) Report of Identification of Select Agent or Toxin, and (5) Request for Exemption.

The Application for Registration (42 CFR 73.7(d)) is used by entities to register with CDC. The Application for Registration requests facility information; a list of select agents or toxins in use, possession, or for transfer by the entity; characterization of the select agent or toxin; and laboratory information. Estimated average time to complete this form is 3 hours, 45 minutes for an entity with one principal investigator working with one select agent or toxin. CDC estimates that entities will need an additional 45 minutes for each additional investigator or agent. In our regulatory analysis, we have estimated that 70% of the 350 entities have 1–3 principal investigators, 15% have 5 principal investigators, and 15% have 10 principal investigators. We have used these figures to calculate the burden for this section. Estimated burden for the Application for Registration is 2,191 hours.

Entities may amend their registration (42 CFR 73.7(h)(1)) if any changes occur in the information submitted to CDC. To apply for an amendment to a certificate of registration, an entity must obtain the relevant portion of the application package and submit the information requested in the package to CDC. Estimated time to amend a registration package is 1 hour.

The Request to Transfer Select Agent or Toxin form (42 CFR 73.16) is used by entities requesting transfer of a select agent or toxin to their facility and by the entity transferring the agent. CDC revised the Request to Transfer Select Agent or Toxin form by removing the requirement that entities provide written notice within five business days when select agents or toxins are consumed or destroyed after a transfer. Estimated average time to complete this form is 1 hour, 30 minutes.

The Report of Theft, Loss, or Release of Select Agent and Toxin form (42 CFR 73.19(a)(b)) must be completed by entities whenever there is theft, loss, or release of a select agent or toxin. Estimated average time to complete this form is 1 hour.

The Report of Identification of Select Agent or Toxin form 42 CFR 73.5(a)(b) and 73.6(a)(b)) is used by clinical and diagnostic laboratories to notify CDC that select agents or toxins identified as the result of diagnostic or proficiency testing have been disposed of in a proper manner. In addition, the form is used by Federal law enforcement agencies to report the seizure and final disposition of select agents and toxins. Estimated average time to complete this form is 1 hour.

The Request for Exemption form (42 CFR 73.5(d)(e) and 73.6(d)(e)) is used by entities that are using an investigational product that are, bear, or contain select agents or toxins, or in cases of public health emergency. Estimated average time to complete this form is 1 hour.

In addition to the standardized forms, this regulation also outlines situations in which an entity must notify or may make a request of the HHS Secretary in writing. An entity may apply to the HHS Secretary for an expedited review of an individual by the Attorney General (42 CFR 73.10(e)). To apply for this expedited review, an entity must submit a request in writing to the HHS Secretary establishing the need for such action. The estimated time to gather the information and submit this request is 30 minutes. CDC has not developed standardized forms to use in the above situations. Rather, the entity should provide the information as requested in the appropriate section of the regulation.

An entity may also apply to the HHS Secretary for an exclusion of an attenuated strain of a select agent or toxin that does not pose a severe threat to public health and safety (42 CFR 73.3(e)(1) and 73.4(e)(1)). The estimated time to gather the information and submit this request is 1 hour.

As part of the requirements of the Responsible Official, the Responsible Official is required to conduct regular inspections (at least annually) of the laboratory where select agents or toxins are stored. Results of these self-inspections must be documented (42 CFR 73.9(a)(5)). CDC estimates, that, on average, such documentation will take 1 hour.

As part of the training requirements of this regulation, the entity is required to record the identity of the individual trained, the date of training, and the means used to verify that the employee understood the training (42 CFR 73.15(c)). Estimated time for this documentation is 2 hours per principal investigator.

An individual or entity may request administrative review of a decision denying or revoking certification of registration or an individual may appeal a denial of access approval (42 CFR 73.20). This request must be made in writing and within 30 calendar days after the adverse decision. This request should include a statement of the factual basis for the review. CDC estimates the time to prepare and submit such a request is 4 hours.

Finally, an entity must implement a system to ensure that certain records and databases are accurate and that the authenticity of records may be verified (42 CFR 73.17(b)). The time to

implement such a system is estimated to average 4 hours.

The cost to respondents is their time to complete the forms and comply with the reporting and recordkeeping components of the Act plus a one-time purchase of a file cabinet (estimated cost $400) to maintain records. The total estimated annualized burden hours are 7,785.

ESTIMATED ANNUALIZED BURDEN HOURS

CFR reference	Data collection instrument	Number of respondents	Responses per respondent	Average burden per response
73.7(d)	Registration Application Form	350	1	3.75
73.7(d)	Additional Investigators	245	2	45/60
73.7(d)	Additional Investigators	53	4	45/60
73.7(d)	Additional Investigators	52	9	45/60
73.7(h)(1)	Amendment to Registration Application	350	2	1
73.19(a)(b)	Report of Theft, Loss, or Release	12	1	1
73.5 & 73.6(d–e)/73.3 & 73.4(e)(1)	Request for Exemption Form/Exclusion	17	1	1
73.16	Request to Transfer	350	2	1.5
73.5 & 73.6(a)(b)	Report of Identification	325	4	1
73.10(e)	Request expedited review	10	1	30/60
73.9(a)(5)	Documentation of self-inspection	350	1	1
73.15(c)	Documentation of training	350	1	2
73.20	Administrative Review	5	1	4
73.17	Ensure secure recordkeeping system	350	1	4

Dated: February 1, 2006.

Betsey Dunaway,

Acting Reports Clearance Officer, Centers for Disease Control and Prevention.

[FR Doc. E6–1694 Filed 2–7–06; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day–06–05AG]

Agency Forms Undergoing Paperwork Reduction Act Review

The Centers for Disease Control and Prevention (CDC) publishes a list of information collection requests under review by the Office of Management and Budget (OMB) in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these requests, call the CDC Reports Clearance Officer at (404) 639–4766 or send an e-mail to *omb@cdc.gov*. Send written comments to CDC Desk Officer, Office of Management and Budget, Washington, DC or by fax to (202) 395–6974. Written comments should be received within 30 days of this notice.

Proposed Project

Process Evaluation of the Protocol for Assessing Community Excellence in Environmental Health—New—National Center for Environmental Health (NCEH), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The CDC, through a cooperative agreement with the National Association of City and County Health Organizations (NACCHO), developed and disseminated the Protocol for Assessing Community Excellence in Environmental Health (PACE EH). This document consists of 13 tasks to engage the community in environmental health planning and assessment activities. PACE EH seeks to strengthen public health leadership, promote community collaboration, and encourage environmental justice. In the long run, PACE EH seeks to establish a new leadership role for local public health agencies and build sustainable community processes for decision-making. More than 1,700 copies of a guidebook have been disseminated to the public and approximately 900 organizations requested one or more copies for review. Little is known about how each of the hundreds of potentially interested communities nationwide evaluates the suitability of the PACE EH methodology to its own situation. Nor do we know the relative advantages and disadvantages each community perceives in this methodology compared to other tools and methods available for conducting environmental health assessments, nor the range of challenges encountered in implementing the method.

The purpose of the proposed study is to obtain information from current and potential PACE EH users that will be used to guide resource decisions related to its continued support and development. Two data collection activities are proposed. The first is a Web survey of all state and local health agencies that requested a copy of the PACE EH Guidebook. The survey will ask questions about their decision whether or not to adopt the method. If they did choose to adopt it, the survey will ask questions about their progress, challenges faced, and impacts of the method on their agency, the community, and the environment. The second data collection activity is a one-day site visit to 24 of the communities that are actively engaged in implementation to conduct interviews with key staff and community members. These site visits will provide additional detail about implementation issues and challenges that are not readily obtained through survey methodology. There is no cost to respondents other than their time. The total estimated annualized burden hours are 846.