Texas Department of Health has received reports of ciguatoxic fish caught on Texas offshore oil rigs, and anecdotal reports to researchers at the University of Texas suggest that the incidence of ciguatera fish poisoning is greater than what has been reported to the Texas Department of Health. We propose to continue to conduct surveillance activities to identify the prevalence of ciguatera fish poisoning in Texas Gulf Coast oil rigs. This study will provide critical data in guiding efforts to characterize the scope of ciguatera poisonings, to identify risk factors, and to prevent an emerging illness associated with reef ecosystems. A questionnaire will be administered over a three-year period to Texas saltwater fishermen (recreational spearfishers and to hook-and-line anglers) who have consumed fish caught on the reef ecosystems off the Texas Gulf coast. There is no cost to respondents other than their time.

ESTIMATE OF ANNUALIZED BURDEN TABLE

Type of respondent	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
Texas Saltwater Fishermen	500	1	20/60	167

Dated: August 30, 2005.

Joan F. Karr,

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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day–05–0576]

Proposed Data Collections Submitted for Public Comment and Recommendations

In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, the Centers for Disease Control and Prevention (CDC) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the data collection plans and instruments, call (404) 371–5983 and send comments to Seleda Perryman, CDC Assistant Reports Clearance Officer, 1600 Clifton Road, MS–D74, Atlanta, GA 30333 or send an e-mail to *omb@cdc.gov.*

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. Written comments should be received within 60 days of this notice.

Proposed Project

Possession, Use, and Transfer of Select Agents and Toxins (OMB Control No. 0920–0576)—Extension—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. The Act specifies that facilities that possess, use, and transfer select agents register with the Secretary. The 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)) will be 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) will be used by entities requesting transfer of a select agent or toxin to their facility, and by the entity receiving 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)) will be 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 will be 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)) will be 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 duties 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.

ESTIMATE OF ANNUALIZED BURDEN HOURS

CFR reference	Data collection	Number of respondents	Responses per respondent	Average hourly burden	Total annual burden (in hours)
73.7(d)	Registration Application	350	1	3.75	1,313
73.7(d)	Additional Investigators	245	2	45/60	368
73.7(d)	Additional Investigators	53	4	45/60	159
73.7(d)	Additional Investigators	52	9	45/60	351
73.7(h)(1)	Amendment to Registration Application.	350	2	1	700
73.19(a)(b)	Notification of Theft, Loss, or Release form.	12	1	1	12
73.5 & 73.6 (d–e)/73.3 & 73.4(e)(1)	Request for Exemption/Exclusion.	17	1	1	17
73.16	Request to Transfer Select Agent or Toxin.	350	2	1.50	1,050
73.5 & 73.6(a)(b)	Report of Identification of Select Agent or Toxin form.	325	4	1	1,300
73.10(e)	Request expedited review	10	1	0.5	5
73.9(a)(5)	Documentation of self-inspection.	350	1	1	350
73.15(c)	Documentation of training	350	1	2	700
73.20	Administrative Review	15	1	4	60
73.17(b)	Ensure secure record-keeping system.	350	1	4	1,400
	Total				7,785

Dated: August 30, 2005.

Joan F. Karr,

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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day–05–05CV]

Proposed Data Collections Submitted for Public Comment and Recommendations

In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, the Centers for Disease Control and Prevention (CDC) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the data collection plans and instruments, call 404–371–5983 and send comments to Seleda Perryman, CDC Assistant Reports Clearance Officer, 1600 Clifton Road, MS–D74, Atlanta, GA 30333 or send an e-mail to *omb@cdc.gov.*

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. Written comments should be received within 60 days of this notice.

Proposed Project

National Survey of 911 Emergency Treatment for Heart Disease and Stroke —New—National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The purpose of this project is to enhance CDC's understanding of emergency medical services (EMS) administration and oversight, identify important stakeholders for partnering and cooperation, and gather data on heart disease and stroke emergency treatment protocols in use. This project will fill an important gap in CDC's understanding of heart disease and stroke emergency medical care by providing detailed information from a sample of EMS organizations on operational resources, configurations of certification levels, treatment protocols and performance measures, and other significant issues at a local and state level in 9 states (FL, MA, KS, MT, NM, PA, OR, SC, AR), in order to ultimately contribute to the development and implementation of best practices for emergency treatment of heart disease and stroke.

The objectives of the data collection are to prepare a comprehensive description of the ''state of the practice'' of pre-hospital emergency medical services related to cardiac and stroke care. This will include organizational and administrative aspects of EMS at state, sub-state district, and local levels, major public and private stakeholders in the conduct of EMS, technical support issues, and practices related to positive outcomes in pre-hospital cardiac and stroke emergency care. Data analysis will include a compilation of the practices in use and comparison of organizational and administrative configurations.

Data collection includes: (1) A telephone survey with a random sample of 250 local EMS agency supervisors (total N=2,250) in each of 9 States on the status of capabilities represented and treatment protocols used in EMS organizations related to cardiac and stroke care; (2) in-person interviews with state level EMS officials (*e.g.*, State EMS Director, State EMS Medical Director, or public health agency representative) (N=18) who are involved in policy and practice of the EMS system in the state and, (3) telephone interviews with a purposive sample five sub-state level EMS officials (*e.g.*, county or district directors) (N=45) in each of the 9 states to examine responsibilities and objectives at a sub-state level for the state's EMS system.

There are no costs to the respondents other than their time.

ESTIMATE OF ANNUALIZED BURDEN HOURS

Respondents	Number of respondents	Number of responses per respondent	Average burden per response (in hrs)	Total burden hours
Survey of Local Level EMS agencies in nine states	2,250	1	15/60	563
Survey of State Level EMS Directors/State Medical Directors in 9 states	18	1	1	18
Survey of Sub-state (district/county) EMS officials in 9 states	45	1	45/60	34
Total				615