SUPPORTING STATEMENT OF THE REQUEST FOR OMB REVIEW AND APPROVAL OF

NATIONAL BLOOD LEAD SURVEILLANCE SYSTEM

National Center for Environmental Health and
National Institute for Occupational Safety and Health

April 16, 2008

A. JUSTIFICATION

A1. Circumstances Making the Collection of Information Necessary

Lead poisoning is a common, preventable environmental disease that can impair the development of young children. The adverse health effects of lead on young children can be profound. High blood lead levels can cause convulsions, coma, and death. Lower lead levels, which rarely cause symptoms, result in decreased intelligence, developmental disabilities, and behavioral disturbances. These consequences are particularly important because they result from levels of lead exposure previously considered safe. Because young children are at highest risk for lead poisoning, CDC recommends that screening programs focus on children less than six years of age.

Adult exposure to inorganic lead occurs when dust and fumes are inhaled and when lead from lead-contaminated hands, food, water, cigarettes, and clothing is ingested. Lead absorbed through the respiratory and digestive systems is released into the blood, which distributes the lead throughout the body. More than 90 percent of total body lead content is accumulated in the bones, where it is stored for decades. Lead in bones continues to be released gradually back into the body long after the external environmental exposure occurs. The health effects of lead on adults at higher exposure levels have been extensively reviewed and shown to damage the central nervous system, the cardiovascular system, the reproductive system, the hematological system and renal system. Studies have also shown that adults with a blood lead level (BLL) of 25-60 µg/dL may exhibit a number of nonspecific symptoms, including irritability, fatigue, headache, sleep disturbance, decreased libido, and depressed mood. A number of studies have reported a variety of adverse health effects such as hypertension, subtle or subclinical central nervous system deficits, and adverse reproductive outcomes in adults exposed to lead at concentrations below existing regulatory exposure limits (40 µg/dL). Although the significance of these subclinical effects on long-term health continues to be studied, the Department of Health and Human Services recommends that BLLs be reduced to <25 µg/dL in all adults by 2010 as a preventive health measure.

In pregnant women, lead readily crosses the placenta. The source of lead exposure for a fetus may be the mother's recent exposure to lead and/or mobilization of lead into the blood during pregnancy from bone stores due to past exposure. The American Conference of Governmental Industrial Hygienists (ACGIH) advises women of child-bearing age that if their BLL is >10 µg/dL, they are at risk of delivering a child with a BLL >10 µg/dL, which is the level of concern in the pediatric CDC guidelines. Although research findings have been inconsistent, some population studies suggest that there may not be a threshold for adverse effects.

The HHS publication, Strategic Plan for the Elimination of Childhood Lead Poisoning, (February 1991) states that a national surveillance program for elevated blood lead levels is "essential for the development of a 'lead priority list' for targeting interventions to reduce environmental exposure to lead, for tracking our progress in eliminating childhood lead poisoning, and for evaluating lead exposure in abatement workers and workers in other

lead-contaminated environments."

State and community health agencies are principal delivery points for childhood lead screening and case management. These agencies receive laboratory reports of children with elevated lead levels and collect demographic information and data on risk factors for lead poisoning during case investigations of these children. Many states do not have resources to independently develop lead surveillance systems that can systematically collect and maintain computerized records from laboratories on blood lead test results, and from environmental departments that conduct inspections and report on remediation activities. In 1992 CDC began awarding cooperative agreements to state and local departments of health or departments of the environment for implementation of childhood blood lead surveillance. CDC currently receives surveillance data from 42 comprehensive Childhood Lead poisoning Prevention Programs (CLPPP) which include patient tracking and blood lead surveillance systems. Forty (40) of these programs have been awarded cooperative agreements by the CDC. The surveillance data is a portion of the larger patient tracking system.

The National Center for Environmental Health (NCEH) in collaboration with the National Institute for Occupational Safety and Health (NIOSH) is requesting a revision of the National Blood Lead Surveillance System (0920-0337) with approval for three more years.

Forty-two childhood lead poisoning prevention programs currently submit their electronic surveillance data files to CDC annually and submit quarterly text reports. Authority for data collection is Section 317A of the Public Health Service Act [42 USC 247b-1] as amended by Section 301 of the "Public Health Service Acts Amendments of 2004" [P.L.102-531]. (Attachment 1). The most recent amendment can be found at: http://energycommerce.house.gov/108/pubs/109_health.pdf

All 40 states in the CDC, NIOSH, ABLES program are required under contract to submit quarterly data files. Authority for data collection for NIOSH was established under the Occupational Safety and Health Act of 1970, 29 U.S.C. 651 et seq. Sections 8 and 20 of the Act describe the investigative, research, and related activities NIOSH is mandated to undertake. NIOSH field investigation regulations and the authorities of NIOSH representatives are set forth in 42 CFR 85 (Requests for Health Hazard Evaluations) and 42 CFR 85a (Occupational Safety and Health Investigations of Places of Employment). (Attachment 2).

A2. Purpose and Use of Information Collection

In 2000, the President's Task Force on Environmental Health Risks and Safety Risks to Children issued a new Federal strategy titled Eliminating Childhood Lead Poisoning: A Federal Strategy Targeting Lead Paint with recommendations to support state-based blood lead surveillance systems and capacity to use data linkage to monitor lead screening in the Medicaid population. This new strategy reinforces the 1991 HHS Strategic Plan for the Elimination of Childhood Lead Poisoning which called for several strategies, including increased Federal support for childhood lead poisoning prevention programs and national

surveillance. The national and state systems are complementary. The purposes of these child blood lead systems are outlined below.

State surveillance and patient tracking:

- monitor case management of individual children with lead poisoning,
- evaluate the productivity and effectiveness of state and local programs,
- identify local program needs such as capacity building in inspection and abatement methods and laboratory services,
- identify clusters of cases to target preventive interventions, and
- identify possible sources of lead and remove or reduce those exposures.

National surveillance:

- track national progress in eliminating childhood lead poisoning,
- track the number of children with lead poisoning to prioritize federal resources,
- evaluate the effectiveness of the CDC grant program,
- assess the effectiveness of state prevention activities to improve interventions, and
- monitor national trends in lead sources exposing children.

As screening activities become more effective at targeting high risk children, the surveillance data will more accurately represent the burden of lead poisoning in the nation. In addition, information collected from surveillance programs will facilitate a comprehensive assessment of prevention effectiveness of childhood lead poisoning prevention activities. Trends can be tracked over time to assess the impact of childhood lead poisoning prevention activities on elimination of this disease. To achieve elimination it will be necessary to remove and/or reduce sources of lead in children's environments. Documentation of all lead sources identified and actions taken to reduce the exposures will be important to track over time.

Since 1987, CDC has sponsored the state-based Adult Blood Lead Epidemiology and Surveillance (ABLES) program to track cases of elevated BLLs among persons ages 16 years and older, and provide intervention consultation and other assistance. The public health objective of the ABLES program, as stated in *Healthy People 2010*, is to reduce the number of persons with BLLs $\geq$25 µg/dL from work exposures to zero by 2010. The ABLES program seeks to accomplish its objective by continuing to improve its surveillance programs and helping state health and other agencies to effectively intervene to prevent further lead exposures. Intervention strategies implemented by ABLES-reporting states include conducting follow-up interviews with physicians, employers, and workers; investigating work sites; delivering technical assistance regarding exposure reduction or prevention; providing referrals for consultation and enforcement; and developing and disseminating educational materials and outreach programs. To coordinate their reporting and intervention activities for maximum efficiency, state ABLES programs are strongly encouraged to develop effective working relationships with the childhood lead prevention programs in their states. An estimated 2-3% of children with BLLs $\geq$10 µg/dL reach those levels from exposure to lead brought home from the workplace on the clothes or in the vehicles of their adult caregivers.

Nationwide data and findings from the ABLES program are periodically published in the CDC's *Morbidity and Mortality Weekly Report* and elsewhere. The most recent report can be found at: http://www.cdc.gov/mmwr/PDF/ss/ss5111.pdf

The quarterly data submission is an electronic data file, containing fields on all children who received lead tests during the previous quarter. The format for this electronic data file is attached (Attachment 3). The report is derived from state child tracking databases of test results submitted by laboratories and follow up data on children with elevated blood lead levels. Personal identifiers are included in the data files transmitted electronically to CDC. Child's name and address are important to unduplicate the multiple tests for children and to unduplicate addresses, the primary source of exposure for most children. In some states, resources may limit ability to perform case investigations on all children with elevated lead levels. Thus, the amount and type of information on each child may vary. States will submit available data, but at a minimum will submit information on child demographics, laboratory test result, appropriate follow-up including repeat testing, and inspections and remediation as appropriate and likely source of lead exposure.

The required data elements for the ABLES program are the same for all adults with blood lead levels of 25 µg/dL or greater (Attachment 4).

The continuation of this data collection will allow CDC to use child tracking and reporting systems already in existence to obtain surveillance data. CDC is developing individual state surveillance reports to guide states in improving the quality of their data so it can help them establish data-based policies and interventions. In 2003, CDC published a report in CDC's *Morbidity and Mortality Weekly Report* which described the national burden of childhood lead poisoning which can be found at: http://www.cdc.gov/mmwr/preview/mmwrhtml/ss5210a1.htm.

A3. Use of Information Technology and Burden Reduction

It is important to note that this data collection does not require the completion of forms. Instead, the states will use computer systems to extract from existing data sources the data elements listed in Attachments 3 & 4 and to transmit these data to CDC. The source data have been furnished to the respondents by laboratories, childhood lead poisoning prevention programs, and other government programs that conduct or reimburse for screening for lead poisoning. Because of variations among states in computer hardware, case volume, and organizational structure, there are no single recommendations for computer hardware or software. This whole process is entirely electronic.

NCEH and NIOSH have collaboratively developed an integrated patient tracking system that states may use to share real-time information across the state. This has made it easier to link adults and children and easier to prepare reports summarizing child and adult prevention activities. The new integrated tracking system has been a part of CDC's National Electronic Disease Surveillance System, which is a Web-based system. Use of this system has made it easier to submit quarterly data files to CDC.

A4. Efforts to Identify Duplication and Use of Similar Information

Through examination of the activities of other government agencies, including, U.S. Environmental Protection Agency (EPA), the Agency for Toxic Substances and Disease Registry (ATSDR), the Health Care Financing Administration (HCFA), the Health Resources and Services Administration (HRSA), and the Department of Housing and Urban Development (HUD), CDC has confirmed that no other national surveillance system for collection of information about children with elevated lead levels presently exists. A literature search confirmed this fact. In consultation with the Occupational Safety and Health Administration (OSHA), NIOSH has determined that no other national surveillance system for collection of information about adults with elevated lead levels presently exists.

The only national data on childhood lead levels presently available are from the National Health and Nutrition Examination Surveys (NHANES). These data were collected between 1976 and 1980, between 1988 and 1994, and again between 1999 and 2002, and are a source of information about the prevalence of elevated lead levels in the U.S. population as a whole. However, the NHANES statistical sampling plan does not permit valid estimates to be made for geographic subsets of the total database. For example, studies demonstrate that inner-city poor children are at higher risk for lead exposure than other children, but sampling is limited in these areas. In addition, these data are not in a format that allows monitoring of short-term trends, calculation of incidence rates, examination of medical treatment, risk factors, or lead sources and remediation among children with elevated blood lead levels, or identification of case clusters. Furthermore, as the prevalence of elevated blood lead levels continues to decrease among children, the sample will identify fewer children with elevated blood lead levels and estimates will become less reliable, thereby increasing the importance of state and local surveillance data to describe trends.

For adults, the NHANES data indicate that by the period 1991-1994, the geometric mean BLL of U.S. adults had dropped to 2.1, 3.1, and 3.4 µg/dL for ages 20-49, 50-69, and 70 and older respectively. This compares to a geometric mean of 13.1 µg/dL for ages 20-74 for the period 1976-1980. Although the mean BLL of the entire U.S. population is relatively low, thousands of adult workers continue to be exposed to high concentrations of lead in more than 100 industries.

A5. Impact on Small Businesses or Other Small Entities

No small businesses will be involved in this study.

A6. Consequences of Collecting the Information Less Frequently

Respondents will submit a quarterly summary data file on all children who received blood

lead tests during the previous quarter. The ABLES program already collects quarterly data on adults and will continue to do so. The collection of these data with this frequency is necessary in order for CDC to monitor short-term trends, to monitor the progress toward elimination of elevated blood lead levels, and to offer programmatic advice and assistance in a timely fashion. There are no legal obstacles to reduce the burden.

A7. Special Circumstances Relating to the Guidelines of 5CFR 1320.5

There are no special circumstances associated with this data collection. The data collection complies with the guidelines of 5 CFR 1302.5.

A8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside Agency

A. The *Federal Register Notice* was published on February 15, 2008, Vol. 73, No. 32 pg 8876-8877. No comments were received.

B. Federal agencies and cooperative agreement recipients are continually consulted regarding the data collected in the national surveillance system. (See below for a listing of individual consultant) Since FY 1993, cooperative agreement recipients participated in yearly meetings in which they discussed topics such as the type of data to be collected, the blood lead level establishing a case for surveillance purposes, the fields in the surveillance database, the format for reporting, and technical assistance on various reporting methods. These issues, plus other concerns raised by the participants, have been addressed. In 1995, the Council of State and Territorial Epidemiologists (CSTE) made elevated blood lead levels among children a nationally notifiable condition. Elevated adult blood lead levels were also made reportable by CSTE in 1995 and the surveillance case definition was updated in 1999 (Attachment 6).

The ABLES program participants also meet yearly and ABLES conducts extensive consultation over its listserv on issues relating to data collection and standardization. ABLES also works in close collaboration with the Council of State and Territorial Epidemiologists (CSTE). Please see Attachment 5 for examples of cooperation with the CSTE, including the Occupational Indicators project 2004, the use of ABLES data to identify the potential need for stricter regulations on adult lead exposures 2001, the establishment of ABLES as the initial core component of state occupational surveillance 2000, and the establishment of the Surveillance Case Definition for Adult Blood Lead Levels (1999) (Attachment 7).

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A9. Explanation of Any Payment or Gift to Respondents

No payments will be provided.

A10. Assurance of Confidentiality Provided to Respondents

The respondents, with the exception of 2, are CDC grant, cooperative agreement or contract fund recipients from official state or territorial health departments, and/or departments of the environment who have received funds for developing and implementing childhood and adult blood lead surveillance systems. Personal identifiers will be included in the data files transmitted electronically to CDC for the quarterly summary data file. CDC will require each child's name and address be submitted because the child identification numbers and address identification numbers were not unique and this has resulted in inaccurate counts. Receiving this information at CDC will allow for more accurate reports to Congress and will be less expensive than providing ongoing training for cleaning and unduplicating data. CDC is sharing address information with HUD and EPA which can be used to assess compliance and enforce regulations to protect children's environments. Respondents use computer systems to extract requested data elements from existing data sources. Thus, the data are part of the recipients' already existing record systems. Stringent safeguarding measures are generally in effect at state or territorial health departments, and only authorized staff will have access to the information.

Privacy Impact Assessment Information

A. A CDC Privacy Act Officer has review this submission and determined that the Privacy Act does apply. The applicable System of Records Notice is 09-20-0147. The data collection and processing procedures described is subject to the Privacy Act because identifiable markers are sent to CDC. All data sent to CDC does contain recognizable personal information.

B. All collected data is secured in a password protected surveillance system. The only three staff members with access to this system include the Epidemiology and Surveillance Section Team Leader, the Data Manager, and the Data Coordinator. No other staff member within the Lead Branch has access to the Lead Poisoning and Prevention Branch's surveillance system. Additionally, transmission of the data from State and local Childhood Lead Poisoning and Prevention Programs is uploaded using MS SQL Server which includes an encoded system that must be read using a particular MS Access program.

C. The data are a part of the recipients' already existing record systems. Stringent safeguarding measures are generally in effect at state or territorial health departments, and only authorized staff will have access to the information. At the CDC only three staff members will have access to these data. These three personnel are listed above. The data will be kept in a password protected encrypted database

system. Programs will be advised to inform participants that demographic and clinic information is stored for programmatic purposes which may include transmission of identifiers to the CDC to aid in federal decision making processes. Paper records will not be kept of said information; only encrypted electronic records will be kept. All information will be stored in a locked electronic system.

D. Data will be treated in a secure manner and will not be disclosed, unless otherwise compelled by law.

A11. Justification for Sensitive Questions

CDC will require each child's name and address be submitted because the child identification numbers and address identification numbers were not unique and this has resulted in inaccurate counts. Receiving this information at CDC will allow for more accurate reports to Congress and will be less expensive than providing ongoing training for cleaning and unduplicating data. For the past 10 years CDC has recommended cleaning data routinely, but there is a large turnover of staff in the state and local programs. CDC is sharing address information with HUD and EPA which can be used to assess compliance and enforce regulations to protect children's environments.

A12. Estimates of Annualized Burden Hours and Costs

A. Each recipient will be requested to submit four (quarterly) summary data files. All respondents have fully operational case-management software programs, either STELLAR or a state-developed package. The estimates below are based on the use of such software, which greatly simplifies data extraction and compilation. In addition, data requested for the surveillance system are already found in lead poisoning prevention programs in state health departments. The burden for these reports is based on estimated time necessary for computer runs and data checking and transmittal.

Estimated Annualized Burden Hours

Type of Respondents	Number of Respondents	No. Responses per Respondent	Average Burden per Response (in hours)	Total Annual Burden (in hours)
State and Local Health Departments for Child Surveillance	42	4	2	336
State and Local Health Departments for Adult Surveillance	40	4	2	320

TOTAL				656

B. Cost to respondents is estimated to be $27.73 per hour. This is based on the average hourly rate of pay at the state level for a computer assistant or programmer (depending on the capability of the state's system) to extract and format data, initiate computer runs, and verify and transmit data. Some respondents' costs will be negligible, because states already collect blood lead data and do not have to incur any additional expenses in order to submit the data to CDC.

Estimated Annualized Burden Costs						
Type of Respondents	Number of Respondents	No. Responses per Respondent	Average Burden per Response (in hours)	Total Burden Hours	Estimated Hourly Wage Rate	Respondent Cost
State and Local Health Departments for Child Surveillance	42	4	2	336	$27.73	$9,317.28
State and Local Health Departments for Adult Surveillance	40	4	2	320	$27.73	$8,873.60
TOTAL						$18,190.88

A13. <u>Estimate of Other Total Annual Cost Burden to Respondents or Record keepers</u>

There are no capital and start-up costs or maintenance costs.

A14. <u>Annualized Cost to the Government</u>

For the child program, five federal employees, two of whom will be contributing on a full-time basis, will carry major responsibility or oversight of the national surveillance system and management and analysis of the data. These employees will spend approximately 8,320 hours per year working on the surveillance program. Using an estimated salary of $35 per hour, personnel costs will total $291,200 annually.

For the ABLES program, one federal employee will be contributing on a full-time basis, and carry major responsibility or oversight of the national surveillance system and management and analysis of the data. Four other federal employees will contribute on a part-time basis for a total of 1.8 FTEs. These employees will spend approximately 3,756 (1.8 x 2087) hours per year working on the surveillance program. Using an estimated salary of $35 per hour, personnel costs will total $131,460 annually.

A15. Explanation for Program Changes or Adjustments

We have reduced the number of respondents for the childhood blood lead surveillance programs from 47 State and Local Health Departments to 42, and have increased the number of ABLES (adult) programs from 37 to 40. As a result of these changes, the annual burden hours have been reduced from 672 to 656.

A16. Plans for Tabulation and Publication and Project Time Schedule

Each state has developed a plan for timely analysis and dissemination of summary data to appropriate state-level agencies and individuals. CDC will analyze the national data set and on an annual basis will disseminate results to the state and in public health publications and other media. CDC will also provide this information to Executive Branch officials, the Congress, childhood lead poisoning prevention constituents, and other Federal, state, and local agencies.

Activity	Time Schedule
States will submit data files quarterly	1-3 months after OMB approval and every 3 months thereafter
Analyze data	Approximately 12 months after OMB approval
Disseminate publication/ Data	Approximately 12 months after OMB approval

A17. Reason(s) Display of OMB Expiration Date is Inappropriate

Exemption from displaying the expiration date for the OMB approval of forms is not being

requested.

A18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to certification for Paperwork Reduction Act submissions.

B. COLLECTION OF INFORMATION EMPLOYING STATISTICAL METHODS

The collection does not involve statistical methods. Children and adults are tested for lead poisoning and laboratories send the blood lead test result to the state and local programs. The programs use the blood lead information to help guide allocation of resources. The blood lead test results are stored in a database and other demographic information and lead source and risk assessment information is also collected. The data files submitted to CDC are a smaller portion of this information.

B.1. Respondent Universe and Sampling Methods

The respondents are the recipients of CDC funds as described in A.1 with the exception of 2 CLPPP programs. All respondents come from the following pool of eligible applicants: the official state or territorial health departments, and/or departments of the environment.

B.2. Procedures for the Collection of Information

Recipients of cooperative agreement awards will be asked to submit a summary data file within 90 days of the end of each quarter of the Federal fiscal year. States will not need to collect additional data.

They will be able to transmit their existing documentation to the information collection system described in this document. As part of case management, programs collect information about potential sources and activities to reduce or remove those sources. CDC will now require child blood lead surveillance data submitted to CDC include the environmental inspection and remediation information that they collect as part of case management.

The requirements for recipients of ABLES contracts which are deliverable (electronically) each quarter are: (1) The data in the prescribed format, (2) a brief narrative report describing any notable lead surveillance activities, and (3) an invoice for payment. Deliverable annually (electronically) by the first quarter of the succeeding calendar year (i.e., 4/30/2008) are: (1) Any necessary data revisions for the entire calendar year 2007 in a complete revised data file and (2) a brief annual narrative report describing notable surveillance activities. All the requirements for recipients of ABLES contracts are specifically laid out in Attachment 5.

B.3. Methods to Maximize Response Rates and Deal with Nonresponse

All states with CDC-funded childhood lead poisoning prevention programs already submit child blood lead surveillance data. However, many states have fields with missing information. CDC is developing reports to provide feedback to each program about the quality of their data. CDC project officers will use these reports to highlight weaknesses in

data and recommend ways to improve the quality of the surveillance data.

B.4. Tests of Procedures or Methods to Be Undertaken

CDC is developing a new way of processing the data submitted by the state and local programs. States have complained that CDC's criteria for accepting data are too restrictive. In response, CDC has developed a more inclusive approach and will provide a report to states showing the difference in cases counted under the old and new system. In addition, CDC is developing new reports to provide more feedback to state and local programs about how their data is processed.

B.5. Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing Data

NCEH Project Officer: Chinaro Kennedy, DrPH, MPH, Team Leader
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ATTACHMENTS TO THE SUPPORTING STATEMENT

Attachment 1: Legislative Authority for Childhood Lead Poisoning Prevention Program – Section 301 of the "Public Health Service Acts Amendments of 2004" [P.L.102-531 and Section 317A, Public Health Service Act (42 USC 247b-1)

Attachment 2: Legislative Authority for Adult Blood Lead Epidemiology and Surveillance Program

Attachment 3: Specifications for Quarterly Lead Surveillance Database Submissions (Childhood Lead Poisoning Prevention Program)

Attachment 4: Data Fields for Adult Blood Lead Epidemiology and Surveillance

Attachment 5: IRB Form 1251, Protocol and email IRB approval

Attachment 6: *Federal Register* Notice

Attachment 7: Council of State and Territorial Epidemiologists Position Statement

Attachment 8: Council of State and Territorial Epidemiologists Paper – “Occupational Health Effect and Biologic Exposure Indicators: Results from the Core States Pilot Project”