Blood Lead Surveillance System (BLSS)

Previously 'Healthy Homes and Lead Poisoning Surveillance System (HHLPSS)'

OMB Control No. 0920-0931 (Expiration Date: 05/31/2018)

Request for Revision

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

Supporting Statement Part A –

Justification

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Part A. Justification

Goal of the information collection: This CDC information collection request (ICR) includes two data collection systems that provide a coordinated, comprehensive, and systematic public health approach to the surveillance and monitoring of blood lead levels (BLLs) for children and occupationally-exposed adults in the U.S. The National Center for Environmental Health (NCEH) supports state and local health departments to collect and report individual-level, laboratory-reported blood lead surveillance data for children less than 16 years of age to the Childhood Blood Lead Surveillance (CBLS) system. The National Institute for Occupational Safety and Health (NIOSH) works with state labor and health departments to collect and report laboratory-based blood lead surveillance data from adults, age 16 years and older, most of whom are occupationally-exposed, to the Adult Blood Lead Epidemiology and Surveillance (ABLES) program.

Intended use of the resulting data: Data generated and analyzed from these two programs provides critical information to monitor trends in BLLs over time. This information is used for program implementation, policy development, and to target population-based interventions to children at high-risk for lead exposure and adults who may be exposed to lead in the workplace.

Methods to be used to collect: State and local health departments submit standardized CBLS data on a quarterly basis via a secure encrypted file transfer protocol (FTP) site. CDC staff import and store the CBLS data on a secure CDC network drive for processing, analysis, and generation of reports. State health and labor departments submit ABLES data on an annual basis through secure email attachments, secure web accounts, or secure encrypted FTP sites that is stored on secure CDC network drives for processing, analysis, and generation of reports. By the end of this reporting period, all ABLES data will be submitted through secure encrypted FTP sites.

Subpopulation of interest: Respondents include state or local agencies, or their bona fide agents, who submit blood lead surveillance data: for children under 16 years of age to NCEH (n=48) and for adults 16 years of age or older, most of whom are occupationally-exposed, to NIOSH (n=40).

How data will be analyzed: Data are analyzed by CDC staff to calculate descriptive statistics and explore factors that may be related to differences in exposure levels by location, potential sources of exposure, and over time.

A.1. Circumstances Making the Collection of Information Necessary

The Centers for Disease Control and Prevention (CDC) is requesting a 3-year Paperwork Reduction Act (PRA) clearance for a revision information collection request (ICR) titled the "**Blood Lead Surveillance System (BLSS)**." BLSS was previously titled "Healthy Homes and Lead Poisoning Surveillance System (HHLPSS)" [OMB Control Number 0920-0931; expiration date: May 31, 2018]. BLSS is a continuation of a long-term collaboration between the National Center

for Environmental Health (NCEH) and the National Institute for Occupational Safety and Health (NIOSH) that has been operating under an approved combined ICR since 2005. Details of the requested revisions are provided in Section A.15.

In summary, the changes to the original ICR are as follows:

1. We request to change the title of the ICR from 'Healthy Homes and Lead Poisoning Surveillance System (HHLPSS)' to '**Blood Lead Surveillance System (BLSS)**' to more explicitly reflect the information collected by the NCEH Childhood Blood Lead Surveillance (CBLS) and the NIOSH Adult Blood Lead Epidemiology and Surveillance (ABLES) Systems.
2. We request to remove the NCEH 'healthy homes' variables from the existing HHLPSS ICR, as this data has never been collected at the national level, and to replace the HHLPSS variable list with the updated CBLS variable list.
3. We request to add specific ABLES data fields to the Healthy Homes and Lead Poisoning Software System (HHLPSS) that is used by many state and local agencies to collect and manage blood lead surveillance data.
4. We request to add 20 new CBLS respondents, over the 40 that were previously approved, due to the addition of newly-funded programs in FY17 and FY18.
5. We request to add 12 new ABLES respondents, over the 28 that were previously approved, due to the additional interest expressed by states for voluntary reporting.
6. We request to increase the annual time burden from 640 hours to 1,226 hours to account mainly for the increase in the number of respondents and for additional adjustments to the estimation. This is an increase of 586 annual burden hours.
7. We are working to integrate the information technology (IT) systems Childhood Blood Lead Surveillance (CBLS) and Adult Blood Lead Epidemiology and Surveillance (ABLES).

The Childhood Blood Lead Surveillance (CBLS) system is maintained by NCEH. The NCEH Childhood Lead Poisoning Prevention Program (CLPPP)'s mission, to eliminate childhood lead poisoning as a public health problem, is aligned with the Department of Health and Human Services' (HHS) Healthy People 2020 (HP2020) goal to reduce blood lead levels (BLLs) in children.[1] This data collection is authorized under Sections 301(a), 317A and 317B of the 1944 of the Public Health Service Act (42 U.S.C. 241) as amended by the 1988 Lead Contamination Control Act. [2] In addition, this program is also authorized under Section 4002 of the Patient

[1] HP2020 objective EH-8 Reduce blood lead levels in children. Available at: https://www.healthypeople.gov/2020/topics-objectives/topic/Environmental-Health/objectives

[2] The 1988 Lead Contamination Control Act amended the Public Health Service Act to authorize the Secretary of Health and Human Services to make grants to state and local governments for the initiation and expansion of community programs designed to: (1) screen infants and children for elevated blood lead levels; (2) assure referral

Protection and Affordable Care Act of 2010 (ACA), Public Law (PL) 111-148, (42 U.S.C. Section 300u-11) and under Section 2204 of the Water Infrastructure Improvements for the Nation (WIIN) Act of 2016 (PL 114-322) (**Attachment 1a**).

The Adult Blood Lead Epidemiology and Surveillance (ABLES) program is conducted by NIOSH. NIOSH's mission is to promote safety and health at work for all people through research and prevention. NIOSH was established under Section 22 (29 USC 671), and its general authority to conduct the data collection is found in Section 20 (29 USC 669), of the 1970 Occupational Safety and Health Act (Public Law 91-596), as amended (**Attachment 1b**). Tracking of occupational hazards, exposures, injuries and illnesses is an integral part of the NIOSH mission. This is central to accomplishing ABLES main public health objective of reducing the number of workers with elevated BLLs aligned with the HP2020 objective OSH-7.[3]

The overarching goal of this information collection is to continue the blood lead surveillance collection for children and occupationally-exposed adults in the U.S. Currently, up to 48 state and local NCEH-sponsored CLPPPs report information to the CBLS system, and NCEH anticipates funding up to 12 more CLPPPs in FY18 (n=60 total). Additionally, up to 40 states will report information to NIOSH ABLES program.

In consideration of program funding and revisions for the future, NCEH and NIOSH published a 60-day Federal Register Notice for a new CBLS-ABLES ICR on April 6, 2017, Vol. 82, No. 65, pp. 16839 (**Attachment 2a**), and the 60-day Federal Register Notice to extend HHLPSS was published on November 8, 2017, Vol. 82, No. 215, pp. 51841 (**Attachment 2b**). In consultation with the OMB Office of Information and Regulatory Affairs (OIRA), the programs have decided to combine all program changes under this single HHLPSS revision ICR.

A.2. Purpose and Use of the Information Collection

This information collection request covers two separate CDC data collection systems with individualized program goals that have been operating under a combined PRA clearance since 2005 (**Attachment 3**). The childhood and adult blood lead surveillance data are collected under different statutory mandates, as mentioned in Section A.1.

Childhood Blood Lead Surveillance (CBLS)

for treatment of, and environmental intervention for, infants and children with such blood lead levels; and (3) provide education about childhood lead poisoning. It requires that grant priority be given to programs which will serve areas with a high incidence of elevated blood levels in infants and children. Available at: https://www.congress.gov/bill/100th-congress/house-bill/4939.

[3] HP2020 objective OSH-7 Reduce the proportion of persons who have elevated blood lead concentrations from work exposures. Available at: https://www.healthypeople.gov/2020/topics-objectives/topic/occupational-safety-and-health/objectives

CDC's CLPPP compiles state surveillance data for children less than 16 years of age into a national CBLS system. More information is available at: https://www.cdc.gov/nceh/lead/data/.

The goal of the NCEH CLPPP is to promote primary prevention of exposure to lead in children, and, as a secondary prevention strategy, to promote blood lead testing and surveillance of BLLs in children to ensure that there is a comprehensive system in place for the identification, referral, case management, and follow-up evaluation of lead-exposed children.

In February 1991, the "Strategic Plan for the Elimination of Childhood Lead Poisoning" (HHS, 1991), recommended four immediately essential elements of the effort to eliminate childhood lead poisoning in the U.S., including establishment of national surveillance for children with elevated BLLs. In 1994, CDC's CLPPP initially proposed and began collecting surveillance data on BLLs in children less than 16 years of age (Pertowski, 1994) [OMB Control Number: 0920-0337; expiration 04/30/2012]. In 1995, the Council of State and Territorial Epidemiologists (CSTE) designated elevated BLLs as the first noninfectious condition to be notifiable at the national level (CDC, 1996; CDC, 2016). However, mandatory laboratory reporting of all blood lead test results, not just "elevated" BLLs, to state health departments is an essential element of successful childhood blood lead surveillance programs because it allows programs to calculate the denominator of children tested in the state.

According to Federal law, all children enrolled in Medicaid are required to receive blood lead tests at ages 12 months and 24 months. Any child between 24 and 72 months with no record of a previous blood lead test must receive a "catch-up" blood lead test. Additionally, states may have their own laws and regulations regarding more stringent requirements for blood lead testing and reporting of blood lead test results to the state health department.

CBLS collects all laboratory and clinician-reported BLL test results on individual children reported to participating state or local CLPPPs. The de-identified, individual-level case management and follow-up data are forwarded to CDC, imported into CBLS, and a consistent "case" definition is then applied. This allows for comparison across programs (jurisdictions) that would otherwise not be possible. Due to differences in jurisdictional screening practices and laboratory reporting requirements, these data do not provide for valid nationally representative incidence or prevalence estimates. However, when a consistent case definition is applied these data are useful for estimating needs at the Federal, state, and local level which is important for establishing national program goals and objectives.

Currently, CDC funds 48 state and local health departments for lead prevention and surveillance activities (**Attachment 4a & 4b**). CDC is also planning to fund up to 12 additional awardees over the next fiscal year (total n=60). As part of the funding agreements, cooperative agreement recipients are required to compile and report blood lead surveillance data to CDC on a quarterly basis. The information is used by CDC to monitor short-term trends, progress toward elimination of lead hazards, and to oversee programmatic activities in a timely fashion.

Population surveillance of children's BLLs provides information on how well we are protecting all children from exposure to lead and also provides critical information needed to identify and care for those individual children who are already exposed. Blood lead surveillance data provide the foundation for targeting prevention activities to high risk areas. A summary of CBLS program milestones and accomplishments is found in **Attachment 5a**.

Adult Blood Lead Epidemiology and Surveillance (ABLES)

CDC's NIOSH compiles state surveillance data for adults 16 years of age or greater, most of whom are occupationally-exposed, by the Adult Blood Lead Epidemiology and Surveillance (ABLES) program. More information is available at: https://www.cdc.gov/niosh/topics/ables/. ABLES is a long-standing state-based surveillance program of laboratory-reported adult BLLs aimed at addressing the national occupational health problem of lead exposure in the workplace. A summary of ABLES program milestones and accomplishments is found in **Attachment 5b**.

In the U.S., over 95% of adults with BLLs over 25 µg/dL are related to occupational exposure. About 90% of these workers are employed in four main industry sectors[4]: manufacturing (NAICS 31-33), construction (NAICS 23), services (NAICS 51-56, 61, 71, 72, 81, 92), and mining (NAICS 21); however, lead is also found in other industries. Moreover, many workers continue to report very high BLLs (above 40 µg/dL) whereas the U.S. national average BLL for adults is 0.967 µg/dL. Pregnant and breastfeeding women employed in lead-related industries may pass lead to their unborn baby or breastfeeding infant. In addition, workers exposed to lead may contaminate their clothing, cars, and homes resulting in lead exposure to their children and others in their household. This is of concern because lead exposure causes acute and chronic adverse effects in multiple organ systems and even BLLs below 10 µg/dL can negatively affect the neurological, cardiovascular, and reproductive systems. Collecting blood lead data from workers is, therefore, needed to track exposures and to identify interventions to reduce or prevent lead exposures.

Per 29 CFR Part 1910 and 29 CFR Part 1926, the Occupational Safety and Health Administration (OSHA) mandates that medical surveillance, including regular blood lead tests, be conducted for workers who are exposed to an airborne concentration of lead of 30 µg/m^3 for 30 or more days. OSHA estimates that approximately 804,000 workers in general industry and an additional 838,000 workers in construction are potentially exposed to lead (OSHA, 2017). In addition, states have reporting laws requiring laboratories and providers to submit blood lead results to the health department. As a result, state health departments collect blood lead data analyzed by laboratories and providers. States then share these data with NIOSH providing a unique

[4] The North American Industry Classification System (NAICS) is the standard used by Federal statistical agencies in classifying business establishments for the purpose of collecting, analyzing, and publishing statistical data related to the U.S. business economy. https://www.bls.gov/bls/naics.htm

opportunity to monitor occupational blood lead data and identify interventions to reduce or prevent occupational lead exposures. While the current reference BLL is <5 µg/dL, obtaining work-relatedness and industry information for adults with BLLs <25 µg/dL is resource intensive because there are many more cases with BLLs <25 µg/dL. Few states are staffed to follow up on these <25 µg/dL cases. Therefore, NIOSH accepts any occupational data that states can provide. Additional details are provided in Section A.3.

Occupational blood lead data are used by states, OSHA, and NIOSH to monitor and develop policies to reduce occupational lead exposure by targeting unsafe conditions or high hazard industries. Case level data are not shared outside NIOSH. Since over 95% of lead exposure is work-related, ABLES data cannot be generalized to the U.S. population. Aggregated data are available via the NIOSH Workers Health Charts[5] and the ABLES website.[6] States use the data to provide guidance and information to workers and employers. States also share data with the OSHA for enforcement and compliance assistance activities. In 2008, OSHA updated its "National Emphasis Program – Lead" to reduce occupational lead exposure by targeting unsafe conditions or high hazard industries. OSHA used ABLES data to identify industries where elevated BLLs indicate a need for increased focus. The data are used to track prevalence of elevated BLLs and provide essential information for setting priorities and goals for research and intervention, such as the HP2020 OSH-7 objective. In 2010, CDC adopted adult blood lead as a national notifiable condition. ABLES data were also used in support of updates to the case definition for an elevated BLL.

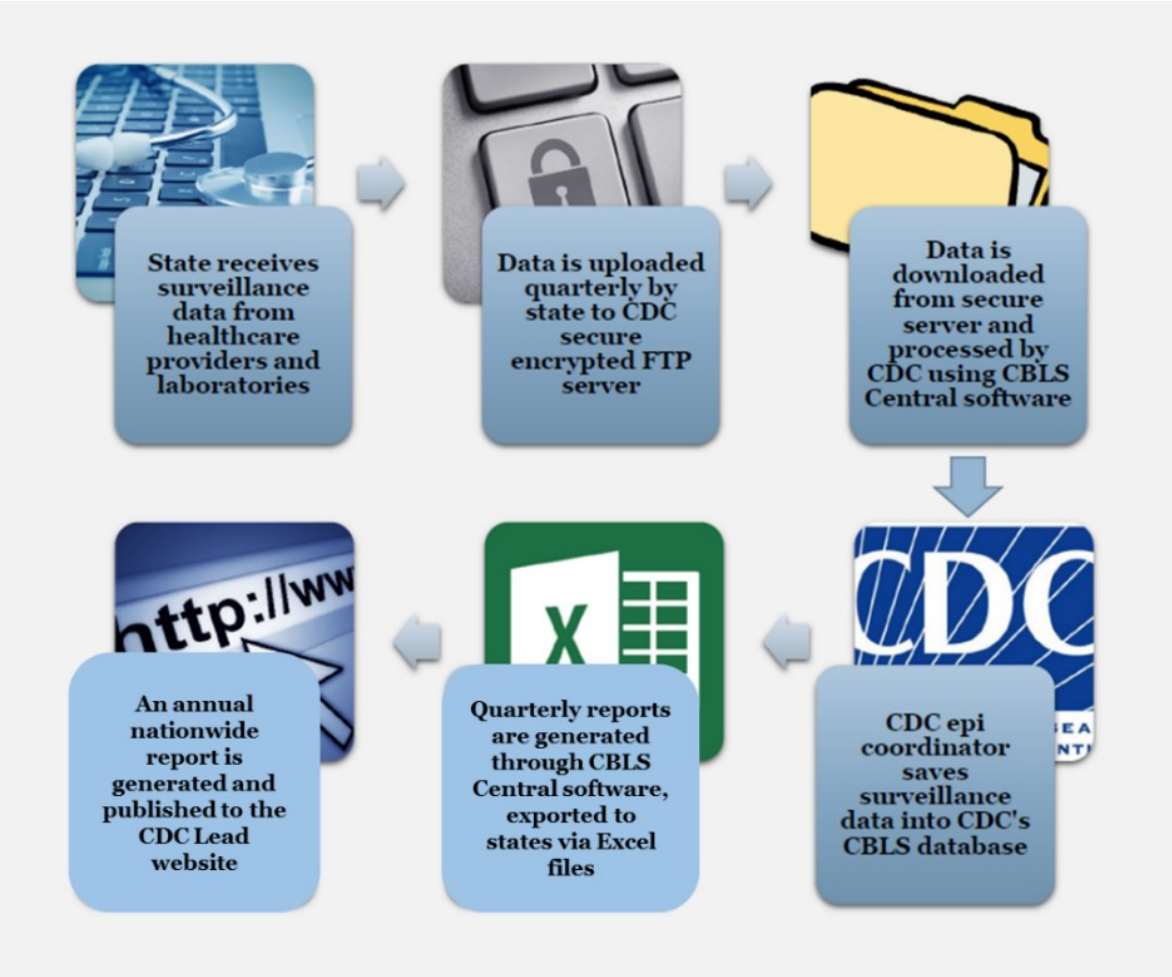
A.3. Use of Improved Information Technology and Burden Reduction

Reporting to the NCEH CBLS System: All CBLS reporting is done by electronic means. CDC software for blood lead surveillance is developed and provided free of charge to state and local programs. Prior to 2007, the software designed and deployed by CDC was called "Systematic Tracking of Elevated Lead Levels and Remediation (STELLAR)." Figure A.3.1 provides a graphical overview of the current CDC-designed and deployed CBLS data collection software. "Healthy Homes and Lead Poisoning Software System (HHLPSS)" is used by most CLPPPs to collect blood lead surveillance and case management follow-up data. HHLPSS includes specialized modules for clinical and environmental follow-up for use at the local level only, such as 'healthy homes' variables (**Attachment 6a**); however, NCEH only requires delivery of blood lead case management and follow-up data. NCEH supports ongoing maintenance and development to assure that the software is up-to-date and meets programs' evolving needs. An additional benefit of using this CDC-deployed software is that surveillance data extracts are built into the

[5] Worker Health Charts : https://wwwn.cdc.gov/Niosh-whc/chart/ables-ab/exposure
[6] ABLES website: https://www.cdc.gov/niosh/topics/ables/data.html

system; however, some programs are required to use state-based IT systems. All respondent-programs have a computerized system for collecting and managing blood lead surveillance data. These programs extract CBLS surveillance data and submit to CDC using the required ASCII- text file format.

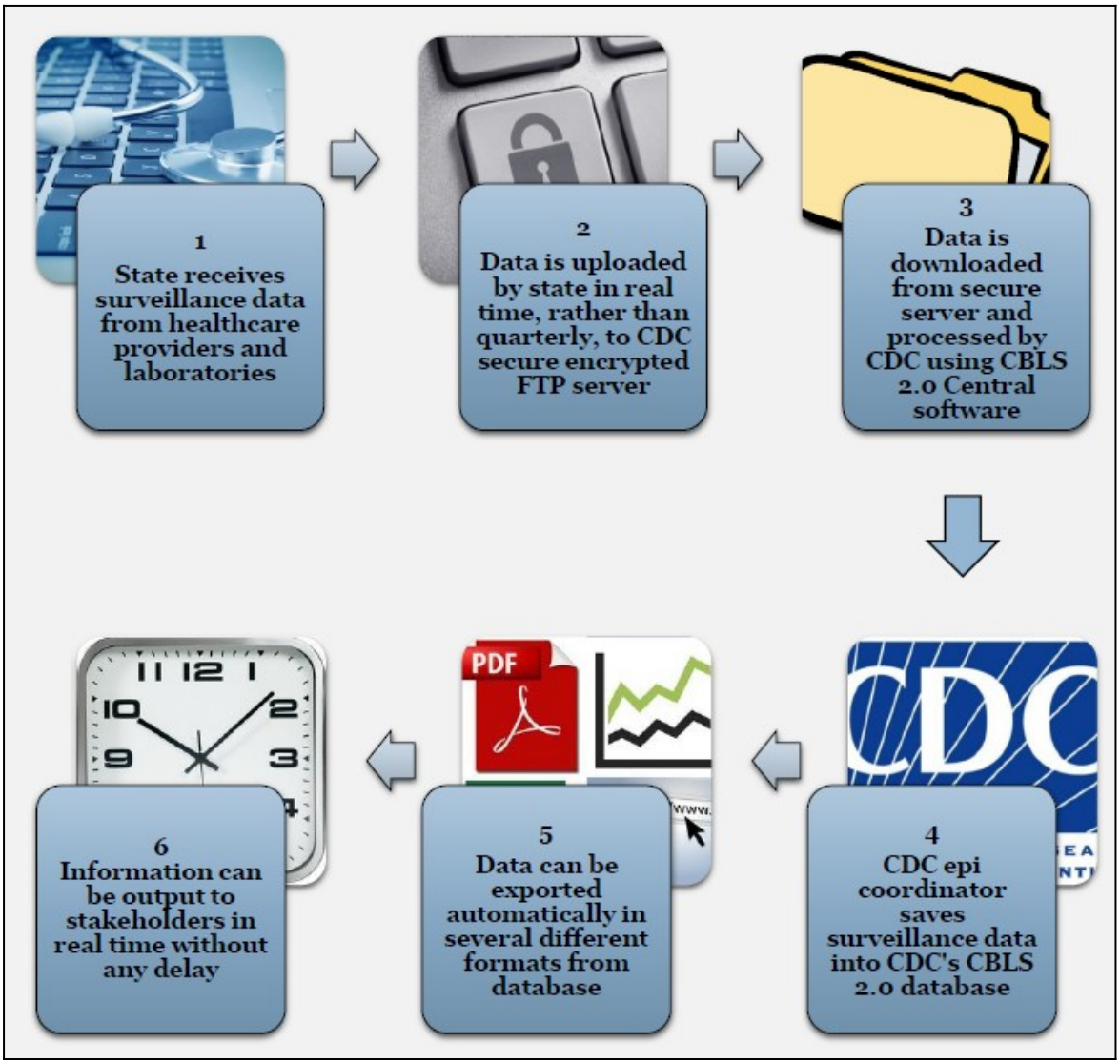
Figure A.3.1. Overview of the Childhood Blood Lead Surveillance System



For the first year of this PRA clearance, 34 FY14/FY17 NCEH respondents will upload CBLS Format: Tables 1-6 only listed in "HHLPSS Variables" (**Attachment 6a**) to the NCEH secure encrypted FTP site, on a quarterly basis with a one quarter lag. After the first year, they will begin reporting "CBLS Variables" text files (**Attachment 6b**). Based on past experience with a single recipient from a local jurisdiction, NCEH also anticipates that one FY14/FY17 respondent will continue to report annual "CBLS Aggregate Records" in electronic spreadsheet format (**Attachment 6c**). Simultaneously, 14 new FY17 and up to 12 new FY18 program recipients will report all program data only as "CBLS Variables" **(Attachment 6b). ** During this overlapping program year, recipients will submit childhood blood lead surveillance data meeting FY14 or FY17 program standards, but not both. A comparison of the variable reporting requirements between the existing approved ICR and proposed new ICR is made in (**Attachment 6d**).

Figure A.3.2 provides an overview of the "Next Generation" CBLS which will be a web-based system that is anticipated to go into production in late 2018. One of the goals of this updated data system is to provide access to information collection in a "near real-time" manner with less of a delay than in previous systems.

Figure A.3.2. Overview of the "Next Generation" Childhood Blood Lead Surveillance System



Reporting to the NIOSH ABLES System: All participating states transmit adult blood lead data to NIOSH in electronic format (e.g., Excel spreadsheet, CSV format, Access database). States collect adult BLL data from laboratories and physicians. Most of these adults are employed in jobs and industries with potential for lead exposure. OSHA mandates lead surveillance of adults occupationally exposed to lead. States follow-up with workers to: confirm industry of employment and occupation; identify work-relatedness of lead exposure; and submit de-identified data annually to NIOSH. Blood lead data transmitted to NIOSH include case-based

records or aggregated tables, and a brief narrative report describing any notable lead surveillance activities. An estimated 80% of states will report case records (**Attachment 7a**) in the required format (**Attachment 7a1**). An estimated 20% of states may lack adequate resources to submit case records and, to accommodate this situation, they send data to NIOSH in aggregated form (**Attachment 7b**). States complete either the case-based form or the aggregated form, but not both.

Over time, NIOSH has made changes to the ABLES standardized variables. (**Attachment 7c**) These changes are: 1) update of the ABLES case definition of an elevated BLL from ≥10 µg/dL to ≥5 µg/dL based on evidence for adverse health outcomes among adults with BLLs as low as 5 µg/dL. This rationale is consistent with CSTE recommendations (CSTE, 2015), and 2) addition of variable definitions and details. Please see Section A.15 for a discussion on the program modifications in this submission.

From 1987-2013, NIOSH provided funding that resulted in the expansion of the ABLES program from 4 to 41 states. However, Federal funding for state ABLES programs was discontinued in September 2013. As of April 2018, 37 states collaborate with NIOSH to conduct adult BLL surveillance, and among them, 23 states have submitted blood lead data for 2016. Since 2016, ABLES has been working with NCEH CBLS program to incorporate adult blood lead information into the Healthy Home and Lead Poisoning Software System (HHLPSS). This ongoing initiative was encouraged by state partners to help them reduce personnel and time burden of data collection and data management. Currently no states entering adult blood lead data are using HHLPSS because the software user-interface is in development.

A.4. Efforts to Identify Duplication and Use of Similar Information

The ICR represents two data collection systems that, when combined, provide a coordinated, comprehensive, and systematic public health approach to the surveillance and monitoring of BLLs for children and occupationally-exposed adults in the U.S. NCEH supports state and local health departments to collect and report individual-level, laboratory-reported blood lead surveillance data for children less than 16 years of age to the CBLS system. NIOSH works with state labor and health departments to collect and report laboratory-based blood lead surveillance data from adults, age 16 years and older, most of whom are occupationally-exposed, to the ABLES program. No other data collection systems provide the level of detail available under this information collection that is used for program implementation, policy development, and to target population-based interventions at the state and local level.

CDC's National Health and Nutrition Examination Survey (NHANES) collects BLLs from a nationally-representative subset of noninstitutionalized adults and children in the U.S. NHANES

data provide the ability to generate a valid estimate of the U.S. population distribution of BLLs (CDC, 2018). Among the statistics generated from NHANES data are the geometric mean BLLs and the national prevalence estimates of BLLs ≥5 µg/dL and ≥10 µg/dL among children and adults. These estimates provide the best available evidence for the U.S. population overall, but the sample size and survey design do not allow for generating estimates at the state or local level. CDC uses BLLs from NHANES to assess national progress towards the HP2020 goals to: 1) reduce BLL in children aged 1–5 years and 2) reduce the mean BLLs in children.

In contrast to NHANEs data on children, CBLS respondents report laboratory and clinician-reported BLL test results on individual children. Although these data cannot be used to generate nationally representative estimates, due to differences in jurisdictional screening practices and laboratory reporting requirements, these data are useful for estimating needs at the Federal, state, and local level when a consistent case definition is applied.

Additionally, unlike NHANES adult data, ABLES data are used to describe adult occupational exposure to lead rather than community exposure. Since over 95% of lead exposure in adults is work-related, ABLES data cannot be generalized to the U.S. population. The sample size and survey design do not allow for generating estimates by industry. The likelihood that a worker exposed to lead on the job may be randomly selected as an NHANES participant is small.

CDC's Environmental Public Health Tracking Program emphasizes web-based dissemination of a large number of various environmental health indicators on environmental hazards, exposures, and health outcomes in aggregate form. [OMB Control Number: 0920-1175; expiration date 04/30/2020]. The Tracking Program annually collects aggregate childhood BLL data by age group, BLL category, and geographic location (county) from its 26 cooperative agreement recipients under CDC-RFA-EH14-1403, CDC-RFA-EH14-1405, and under CDC-RFA-EH17-1702.

CBLS data are fundamentally different from the Tracking Program annual aggregate counts because CBLS collects de-identified, individual-level data used for program management and public health intervention at the state and local level. There is some duplication of effort between CBLS and the Tracking Program, since some states that participate in both CDC Programs; however, the duplication is minimal as the data required by the Tracking Program is readily available among CBLS recipients. Currently, there are four states that are part of Tracking Program, and not part of CBLS, but within these four states CDC supports two local jurisdictions for CBLS. The Notices of Funding Opportunity (NOFOs) that guide the Tracking and CBLS program goals and requirements are not on the same schedule, so the overlap between these two programs changes over time. Additionally, some states have data sharing agreements with CDC that must be modified before sharing between CDC programs can occur. With a recently approved administrative reorganization [FRN Vol 83 No 30; 02/13/2018], these two CDC programs have been merged into one branch, the Lead Poisoning Prevention and

Environmental Health Tracking Branch, within NCEH and efforts to coordinate data collections for lead are currently underway.

The Centers for Medicare & Medicaid Services (CMS) requires that all children enrolled in Medicaid receive blood lead screening tests at ages 12 months and 24 months.[7,8] In addition, any child between ages 24 and 72 months with no record of a previous blood lead screening test must receive one. The Medicaid requirement is met only when one of the two blood lead screening tests identified above (or a catch-up blood lead screening test) are conducted. These test results are captured by State-based CLPPPs, where these programs exist and as state-based blood lead reporting laws require. State Medicaid agencies are required to submit Early Periodic Screening, Diagnosis, and Treatment (EPSDT) data annually using Form CMS-416, line 14[9] [Annual EPSDT Participation Report; OMB Control Number: 0938-0354; expiration date 06/30/2020], including the total aggregate number of blood lead screening tests for children enrolled in Medicaid, from birth to age 6 years.

CBLS data fundamentally differ from the CMS data in that CBLS is more complete because it does not restrict test results to those on children of a certain age or socioeconomic status. In addition, as stated previously, CBLS data represent individual-child data that is de-identified prior to submission as opposed to aggregate counts of tests or children tested.

A.5. Impact on Small Businesses or Other Small Entities

The collection of this information does not directly impact small businesses or small entities. CDC collects only the minimum data necessary to carry out the goals for CBLS and ABLES directly from state and local agencies or their bona fide agents.

A.6. Consequences of Collecting the Information Less Frequently

There are no technical or legal obstacles to reducing burden.

As part of program requirements, respondents will submit their data quarterly to CBLS. Prior to 2005, childhood blood lead surveillance data (on individual children's blood lead tests) was collected annually at the end of the 1st quarter of the subsequent calendar year and programmatic data (aggregate counts of the number of children tested) were collected quarterly to monitor program progress towards strategic goals (such as prevention activities including: blood lead screening, follow-up testing, and identification and mitigation of lead

[7] CMS: Accessed 01/27/2017 at https://www.medicaid.gov/federal-policy-guidance/downloads/cib113016.pdf
[8] CMS: Accessed 01/27/2017 at https://www.medicaid.gov/federal-policy-guidance/downloads/cib-06-22-12.pdf
[9] CMS: Accessed 01/27/2017 at https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/Downloads/CMS416.pdf

sources). In 2005, based on feedback received from state partners, the decision was made to increase the frequency of surveillance data collection from once a year (on an annual basis) to four times a year (on a quarterly basis) to supplant the need for separate quarterly programmatic reporting. CBLS currently uses quarterly surveillance data is for technical assistance and program management purposes and updates the childhood blood lead reports once a year when the updated information is posted to the general public website.

The ABLES program updates the adult blood lead database once a year and reports are shared with federal agencies, states, and the general public annually.

A.7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

There are no special circumstances with this information collection package. This request fully complies with the regulation 5 CFR 1320.5.

A.8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

NCEH and NIOSH published a 60-day Federal Register Notice for a new CBLS-ABLES ICR on April 6, 2017, Vol. 82, No. 65, pp. 16839 (**Attachment 2a**). A 60-day Federal Register Notice to extend HHLPSS was also published in the *Federal Register* on November 8, 2017, vol. 82, No. 215, pp. 51841 (**Attachment 2b)**. In consultation with the OMB Office of Information and Regulatory Affairs (OIRA), the programs have decided to combine all program changes under this single HHLPSS revision ICR. CDC did not receive public comments related to either of these notices.

CBLS regularly engages with outside consultations with experts and stakeholders during the:

- biannual meetings of NCEH/ATSDR Board of Scientific Counselors (BSC) (https://www.atsdr.cdc.gov/science/members.html);
- ad hoc meetings of the BSC Lead Poisoning Prevention Subcommittee (https://www.atsdr.cdc.gov/science/lpp/lppmembership.html); and
- annual meeting of state and local cooperative agreement recipients (https://www.cdc.gov/nceh/lead/programs/)
- monthly meetings of the Lead Subcommittee of the President's Task Force for Environmental Health and Safety Risks to Children (https://ptfceh.niehs.nih.gov/activities/lead-exposures/)

During the past three years, CBLS has specifically engaged in consultations with:

NCEH/ATSDR Board of Scientific Counselors (as of 01/30/2017)

CHAIR **Melissa J. Perry ScD, MHS** Fellow of the American College of Epidemiology Professor and Chair of Environmental and Occupational Health, and Professor of Epidemiology Milken Institute School of Public Health Professor of Biochemistry and Molecular Biology School of Medicine and Health Sciences The George Washington University Term: 2/3/14 - 6/02/17	**DESIGNATED FEDERAL OFFICER** **William Cibulas, PhD, MS** Deputy Associate Director for Science, National Center for Environmental Health/Agency for Toxic Substances and Disease Registry
MEMBERS	
Kenneth Aldous, PhD Wadsworth School of Laboratory Sciences Term: 6/3/2016- 6/2/2020	**Aaron Bernstein, MD MPH** Harvard School of Public Health Term: 6/3/2016- 6/2/2020
Darryl Brown, PhD MPA Drexel University School of Public Health Term: 6/2/2015 - 6/2/2019	**Suzanne Condon, MSM** Massachusetts Department of Health Term: 6/2/2015 - 6/2/2019
Deborah A. Cory-Slechta, Ph.D. Professor, Department of Environmental Medicines and Pediatrics, University of Rochester School of Medicine Term: 5/2/15 – 6/2/18	**Kim N. Dietrich, Ph.D.** Professor of Environmental Health, University of Cincinnati College of Medicine, Department of Environmental Health Term: 4/30/15 – 6/2/18
Roberta Grant, PhD TCEQ Term: 6/2/2015 - 6/2/2019	**Sharron E. LaFollette, PhD** Emeriti Professor and Chair, Department of Public Health, University of Illinois at Springfield Term: 4/29/15 – 6/2/18
Joyce M. Martin, MA JD JM Environmental Health Consulting Term: 6/3/2016- 6/2/2020	**Ralph McCullers, MPA** Compliance and Enforcement Division Clark County Department of Air Quality Term: 6/3/2016- 6/2/2020
John Meeker, ScD, CIH University of Michigan Term: 6/2/2015 – 6/2/2017	**Devon Payne-Sturges, DrPH MPH** University of Maryland Term: 6/2/2015 - 6/2/2019
Matthew J Strickland, PhD MPH School of Community Health Sciences, University of Nevada, Reno Term: 2/3/14 - 6/02/17	**Phillip L. Williams, PhD** Dean, College of Public Health, University of Georgia, Coverdell Center Term: 2/6/14 - 6/02/17
Nsedu Obot Witherspoon, MPH Executive Director, Children's Environmental Health Network Term: 4/27/2015 – 6/2/2018	
FEDERAL EXPERTS	
Wayne E. Cascio, MD, FACC, FAHA Director, Environmental Public Health Division National Health and Environmental Effects Research Laboratory Office of Research and Development, U.S. EPA EPA Human Studies Facility	**Bonnie S. Richter, MPH, PhD** Senior Epidemiologist, Office of Health and Safety. HS-13, U.S. Department of Energy
Kristina Thayer, PhD Director, NTP Center for the Evaluation of Risks to	**Douglas Trout, MD** Associate Director for Science, Division of Surveillance,

Human Reproduction (CERHR), NIEHS/NTP	Hazard Evaluations & Field Studies, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention

NCEH/ATSDR BSC Lead Poisoning Prevention Subcommittee (as of 01/30/2017)	
CHAIR **Matthew Strickland, BA, MA, MPH, PhD.** School of Community Health Sciences University of Nevada - Reno	**DESIGNATED FEDERAL OFFICER** **William Cibulas, PhD, MS, CAPT** Deputy Associate Director for Science National Center for Environmental Health / Agency for Toxic Substances and Disease Registry
MEMBERS	
John G. Belt, MS Chief, Field Services Section Childhood Lead Poisoning Prevention Ohio Department of Health	**Elizabeth A. Colón** Childhood Lead Action Project Parent Educator
Kim N. Dietrich, Ph.D. Professor of Environmental Health University of Cincinnati College of Medicine Department of Environmental Health	**Nathan M. Graber, MD, MPH, FAAP** Director, Center for Environmental Health New York State Department of Health
Michael J. Kosnett, MD, MPH Associate Clinical Professor Division of Clinical Pharmacology & Toxicology, Department of Medicine University of Colorado School of Medicine, and Department of Environmental and Occupational Health, Colorado School of Public Health	**Jennifer A. Lowry, MD** Children's Mercy Hospital Division of Clinical Pharmacology and Medical Toxicology
Patrick J. Parsons, PhD, Chem., FRSC Chief, Laboratory of Inorganic and Nuclear Chemistry, Deputy Director, Division of Environmental Health Sciences Wadsworth Center New York State Department of Health	
FEDERAL EXPERTS	
Mark A. Maddaloni, MS, DrPH Senior Toxicologist U.S. Environmental Protection Agency	

Federal and state partners of the ABLES program meet at the Council of State and Territorial Epidemiologists (CSTE) (http://www.cste.org/) annual conference to exchange experiences and provide feedback on the ABLES program. In addition, state partners participate with NIOSH and NCEH in the ongoing process of integrating ABLES into HHLPSS.

ABLES Contact References

a. Susan Payne – California Department of Public Health, (510) 620-5733
b. Kathy Leinenkugel – Iowa Department of Public Health, (515) 281-4930
c. Barbara Grajewski – Wisconsin Division of Public Health, (608) 266-0923

A.9. Explanation of Any Payment or Gift to Respondents

CBLS respondents are funded through a cooperative agreement (CDC-RFA-EH14-1408PPHF14 and/or CDC-RFA-EH17-1701-PPHF17, **Attachment 4a & 4b**) to develop and sustain programs aimed at childhood lead poisoning prevention and surveillance. CBLS data submission on a quarterly basis is a requirement of these agreements. Cooperative agreement recipients will not receive additional payments or gifts for providing information.

Data submission to the ABLES Program is voluntary and completed through data sharing agreements with state agencies or their bona fide agents.

A.10. Protection of the Privacy and Confidentiality of Information Provided by Respondents

CBLS: The NCEH/ATSDR PRA Contact has reviewed this revision ICR and has determined that the Privacy Act does apply. The applicable Privacy Act System of Records Notice is SORN 09-20-0136 "Epidemiologic Studies and Surveillance of Disease Problems" (retrievable by name and ID number).[10] On October 4, 2017, the NCEH/ATSDR Information Systems Security Officer (ISSO) conducted an annual review of the CBLS and has determined that a new CDC Security Assessment and Authorizations (SA&A) is required. The FY17 CBLS data collection will not begin until the Authority to Operate (ATO) is granted (**Attachment 8a**).

State or local health departments receive data from health care providers, laboratories, hospitals, or other facilities that analyze blood samples for lead and then store these data on secured servers housed on their respective premises. Reporting is conducted through a variety of modes following the specific jurisdiction's system design including: 1) Health Level 7 (HL7) data format via secure, encrypted transfer; 2) Excel sheets via secure, encrypted FTP; or 3) secure delivery of paper records, such as via secure fax. Health departments are responsible for following all local or state personal privacy protection laws and state IT security protocols and processes, such as security options to enter data into password-protected Microsoft SQL databases.

This reporting from providers and laboratories to State or local CLPPPs is not included in the burden table in section A.12., consistent with 5 CFR §1320.3(b)(2) and (b)(3),[11] because the initial collections and reporting to the state is required by state and/or local public health law,

[10] See https://www.cdc.gov/SORNnotice/09-20-0136.htm.

[11] 5 CFR § 1320.3 – Definitions: For purposes of implementing the PRA, the following terms are defined as follows in Paragraph (b):
(2) The time, effort, and financial resources necessary to comply with a collection of information that would be incurred by persons in the normal course of their activities (e.g., in compiling and maintaining business records) will be excluded from the "burden" if the agency demonstrates that the reporting, recordkeeping, or disclosure activities needed to comply are usual and customary.

statutes, or regulations that require blood lead testing and reporting within state or local jurisdictions independent from CDC's consolidation of this information (NCSL, 2010). The reporting, recordkeeping, or disclosure activities needed to comply within jurisdictions are usual and customary, and would be required by law even in the absence of the federal requirement.

As part of funding agreements, CBLS recipients are required to submit quarterly data to CDC with a one-quarter lag (e.g. data collected during the first quarter is due by the end of the second quarter). All required data are extracted from the respondent's secure server and transmitted to CDC via a secure FTP site. Data submitted in text files to CDC are processed and maintained in the CBLS database. Data are delivered in separate text files following formatting requirements then processed using CBLS Central software into linkable tables (FY14 programs - for one year –CBLS Format: Tables 1-6 only listed in "HHLPSS Variables" **Attachment 6a**); FY17 & FY18 programs – **Attachment 6b**). For the regular quarterly CBLS data submissions, all children are assigned a unique child identifier by the state or local program based on the date of birth, unique address identifier (ID), and certain medical information (blood lead test results only). CBLS does <u>not</u> collect any personally identifiable information (PII) including but not limited to: child name, address, phone numbers, medical record or other identification numbers, or financial account information.

Each record contains a file identifier (FILEID), a program identifier (PGMID), and record-specific information to create a unique record identifier. Each table has one or more key variables that can be used to join/merge the data between multiple tables. Three important key variables for linking tables are: 1) Program ID – identifies the recipient jurisdiction; 2) Child ID; and 3) Address ID, which in combination are used to create a unique ID per individual or per address. In FY14, a single local recipient reported annual summary "CBLS Aggregate Records" in spreadsheet format (**Attachment 6c**). We anticipate this recipient will continue to report in aggregate.

In special circumstances when state or local programs request technical assistance from CDC, or CDC makes a data request for its own sponsored projects, CDC will receive data that may include additional IIF that may be linked to the CBLS records delivered in the quarterly reports. In those situations, data will be transferred to CDC via secure FTP in the same manner as the quarterly data submissions. Data will be maintained on secure CDC servers. Each request outside of the CBLS quarterly collection will undergo a separate research and PRA determination and is not covered by this ICR. The ability to receive IIF will be approved when

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(3) A collection of information conducted or sponsored by a Federal agency that is also conducted or sponsored by a unit of State, local, or tribal government is presumed to impose a Federal burden except to the extent that the agency shows that such State, local, or tribal requirement would be imposed even in the absence of a Federal requirement.

the CDC Security Assessment and Authorization (SA&A) for CBLS is completed. The CBLS data collection will not begin until the Authority to Operate (ATO) is granted. Social security numbers are not provided to nor requested by CDC.

If there is a security breach for the CBLS data stored at CDC, some effect on the respondent's privacy could occur; however, to minimize this risk, there are a variety of safeguards in place as described in the applicable Privacy Act System of Records Notice (SORN 09-20-0136 "Epidemiologic Studies and Surveillance of Disease Problems").[12]

No consent form for the CBLS collection is required as the data are part of state or local surveillance efforts, under the Health Insurance Portability and Accountability Act of 1996 (HIPAA) section on disclosures for public health activities.[13] Consent to share data with other federal agencies is not required when it involves enforcement of the Federal Lead Disclosure Rule Section 1018 of Title X and Lead-Safe Housing Rule (24 CFR Part 35)[14].

All CBLS data is secured in a password-protected surveillance system. Only CDC staff will have access to the raw data in CBLS. Data from State or local programs are sent electronically to CDC via a secure FTP site. Physical controls will also be implemented. Data will be stored on highly-secured CDC servers in Atlanta, GA. Access to all CDC campuses is restricted by armed guards. The servers are housed in a secure computer room complete with climate control, emergency power, and an uninterruptible power supply (UPS). Daily back-ups and integrated security are implemented through the CDC computer services infrastructure. All data access is password-protected, and all network communications use encryption. All servers and PCs that are part of the CDC infrastructure are protected by both host-based firewalls and software in order to prevent the undetected installation of "spyware."

ABLES: States collect data on adult BLLs and provide NIOSH with the minimum number of fields that are needed for NIOSH to process and analyze the data. To protect individuals' privacy, NIOSH does not receive data that would directly identify individuals. The data collection does not qualify as a System of Records and is not covered under the Privacy Act. However, the data are considered to be personally identified information (PII) due to its potential identifiability and inclusion of date of birth and an id field which each state provides and which the states can use to identify individuals. See **Attachment 8b** for Privacy Impact Assessment of the system that includes the ABLES project.

NIOSH collects the date of birth to calculate age since state and local health departments vary in their rounding methods. NIOSH uses the ID field for analysis and for communicating with the states regarding data quality issues.

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[12] See https://www.cdc.gov/SORNnotice/09-20-0136.htm.

[13] See https://www.gpo.gov/fdsys/pkg/CFR-2011-title45-vol1/pdf/CFR-2011-title45-vol1-sec164-512.pdf and the discussion of 45 CFR 164.512(b) at https://privacyruleandresearch.nih.gov/pdf/ocr_publichealth.pdf.

[14] See Final Rule - 24 CFR Part 35 - Lead Safe Housing Rule; Docket No. FR–5816–F–02]. Available at: https://www.gpo.gov/fdsys/pkg/FR-2017-01-13/pdf/2017-00261.pdf

Data are stored on CDC facilities, using CDC data network within CDC's firewalls. The CDC network is located in a limited access server room in a building secured with guards, id badges, key cards and closed circuit TV. Access to project data is granted to badged staff assigned to the project and on a need to know basis. User access is removed upon transfer or termination.

State agencies (departments of health or labor departments) share adult BLLs with the NIOSH ABLES program for occupational surveillance under data sharing agreements. States submit adult BLLs through encrypted FTP sites.

A.11. Institutional Review Board (IRB) and Justification for Sensitive Questions

The NCEH/ATSDR Human Subjects coordinator has reviewed the existing CBLS FY14 cooperative agreement (CDC-RFA-EH14-1408-PPHF14) and the new FY17 three-year cooperative agreement (CDC-RFA-EH17-1701-PPHF17) and has determined that this program is non-research; therefore, review and approval by the CDC Institutional Review Board (IRB) is not required (**Attachment 9a**). The NIOSH Human Subjects coordinator has determined that the ABLES collection is non-research and that review and approval by the NIOSH IRB is not required (**Attachment 9b**).

- The purpose of these activities is to identify and control a health problem, specifically lead exposures that may lead to adverse health outcomes for children and adults.
- Intended benefits of the projects are primarily or exclusively for the children and adult workers at risk for lead exposure.
- The data collected are needed for State or local health departments to identify children and adults in need of referral for medical monitoring or management.
- The knowledge that is generated does not extend beyond the scope of the activities and project activities are not experimental.

<u>Justification for Sensitive Questions:</u>

Questions that could be considered sensitive by at least a segment of the population, such as information on pregnancy and race/ethnicity, are integral to accomplishing the purpose of CBLS and ABLES. Table A.11.1 describes the specific use of the potentially sensitive questions.

Table A.11.1. Specific Uses of Questions of a Sensitive Nature

Questions	Specific uses of information
Pregnant at time of test? (at time of blood lead test)	To assess prevalence of pregnant women with elevated blood lead which provides important data for clinical follow-up of women and their unborn babies.

Race/ethnicity?	For targeting resources to subpopulations with high risk for elevated blood lead or housing risk factors

A.12. Estimates of Annualized Burden Hours and Costs

The total annualized time burden requested by the CDC for this ICR is 1,226 hours. This is a 586 hour increase from the previously approved 640 hours for HHLPSS ICR [OMB Control Number: 0920-0931; expiration date 05/31/2018]. We are requesting to include up to 60 CBLS respondents and up to 28 ABLES respondents. The previous OMB submission estimated the combined burden hours and costs for ABLES and CBLS. In this current submission, burden hours and costs are provided separately for CBLS and ABLES by data collection method (individual records and aggregate records).

CBLS Respondents: NCEH respondents include up to 60 cooperative agreement recipients from state or local health departments, or their bona fide agents, who receive support to develop and implement a CLPPP. There are three types of NCEH respondents. First, are the 34 cooperative agreement partners who are both existing FY14 and FY17 awardees. Second, are the 14 additional cooperative agreement awardees funded solely under the FY17 program. Third, NCEH anticipates FY18 funding for up to 12 additional awards. This is an increase of 20 respondents over the 40 previously approved (n=60 total).

For the first year of this PRA clearance, 33 existing FY14/FY17 awardees will report HHLPSS Variables under a FY14 Year 4 program cost extension (4 hours times 12 months divided by 36 months = 1.33 average burden hours per response, rounded down to 1 hour per response) (**Attachment 6a**), and then report CBLS Variables for the FY17 program Years 2 and 3 (4 hours times 24 months divided by 36 months – 2.67 average burden hours per response, rounded up to 3 hours per response)(**Attachment 6b**). These 33 FY14/FY17 respondents will submit quarterly text files of case records (132+396=528 annualized burden hours).

A single local FY14/FY17 recipient will continue to report annual summary "CBLS Aggregate Records" in spreadsheet format using 2 annualized burden hours (**Attachment 6c**).

Also in the first year of this PRA clearance, 14 new FY17 respondents and up to 12 new FY18 respondents will submit quarterly using only the CBLS Variables text file format for case records (224+192=416 annualized burden hours)(**Attachment 6b**).

In the second and thirds years of this PRA clearance, 47 FY17 and up to 12 FY18 respondents (n=59) will submit quarterly CBLS text files (944 annualized hours)(**Attachment 6b**). The total annual time burden requested by NCEH is 946 hours for each year of PRA clearance. Table A.12.1 shows that the Year One and the Years Two and Three have the same time burden despite the current and anticipated changes in program funding.

ABLES Respondents: Over the next three years, up to 40 participating states will submit adult BLL data to NIOSH. Currently, 28 states report BLL data to NIOSH. During this period, NIOSH aims to collaborate with up to 12 additional states. The total burden hours are calculated for 40 respondents. On an annual basis, states submit either case records or aggregate counts of adult blood lead test results (**Attachments 7a, 7a1, 7b**). NIOSH estimates that 80 percent of states (respondents) (n=32) will spend 256 burden hours submitting case records and 20 percent (n=8) will spend 24 burden hours submitting aggregate records. The total annual time burden requested by NIOSH is 280 hours (Table A.12.1).

Table A.12.1. Estimated Annualized Burden Hours

Year One of PRA Clearance

Data Collection	Type of Respondents	Form Name*	No. of Respondents	No. of Responses per Respondent	Average Burden per Response (in hours)	Total Burden Hours
CBLS	FY14/FY17 State or Local Health Departments, or their Bona Fide Agents	HHLPSS Variables	33	4	1	132
		CBLS Variables (ASCii Text Files)	33	4	3	396
		CBLS Aggregate Records (Excel)	1	1	2	2
	Solely FY17 State or Local Health Departments, or their Bona Fide Agents	CBLS Variables (ASCii Text Files)	14	4	4	224
	Solely FY18 State or Local Health Departments, or their Bona Fide Agents	CBLS Variables (ASCii Text Files)	12	4	4	192
ABLES	State or Local Health Departments, or their Bona Fide Agents	ABLES Case Records Form and Brief Narrative Report	32	1	8	256
		ABLES Aggregate Records Form and Brief Narrative Report	8	1	3	24
Total						1,226

Year Two and Three of PRA Clearance

Data Collection	Type of Respondents	Form Name*	No. of Respondents	No. of Responses	Average Burden per	Total Burden

				per Respondent	Response (in hours)	Hours
CBLS	All FY17 and FY18 State or Local Health Departments, or their Bona Fide Agents*	CBLS Variables (ASCii Text Files)	59	4	4	944
		CBLS Aggregate Records (Excel)	1	1	2	2
ABLES	State or Local Health Departments, or their Bona Fide Agents	ABLES Case Records Form and Brief Narrative Report	32	1	8	256
		ABLES Aggregate Records Form and Brief Narrative Report	8	1	3	24
Total						1,226

The total annualized burden cost is $47,066.14 which includes $36,316.94 for CBLS and $10,749.20 for ABLES (Table A.12.2). The hourly wage for respondents is estimated to be $38.39 per hour. This is based on the Bureau of Labor Statistics May 2016 median hourly rate of pay for a computer programmer (see http://www.bls.gov/oes/current/oes151131.htm).

> 15-1131 Computer Programmers - Create, modify, and test the code, forms, and script that allow computer applications to run. Work from specifications drawn up by software developers or other individuals. May assist software developers by analyzing user needs and designing software solutions. May develop and write computer programs to store, locate, and retrieve specific documents, data, and information.

Table A.12.2. Estimated Annualized Burden Costs

Data Collection	Type of Respondents	Form Name*	No. of Respondents	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
CBLS	FY14/FY17 State or Local Health Departments, or their Bona Fide Agents	HHLPSS Variables	33	132	$38.39	$5,067.48
		CBLS Variables (ASCii Text Files)	33	396	$38.39	$15,202.44
		CBLS Aggregate Records (Excel)	1	2	$38.39	$76.78
	Solely FY17 State or Local Health Departments, or their Bona Fide Agents	CBLS Variables (ASCii Text Files)	14	224	$38.39	$8,599.36
	Solely FY18 State or Local Health Departments, or	CBLS Variables (ASCii Text Files)	12	192	$38.39	$7,370.88

	their Bona Fide Agents					
ABLES	State or Local Health Departments, or their Bona Fide Agents	ABLES Case Records Form and Brief Narrative Report	32	256	$38.39	$9,827.84
		ABLES Aggregate Records Form and Brief Narrative Report	8	24	$38.39	$921.36
Total						$47,066.14

A.13. Estimates of Other Total Annual Cost Burden to Respondents and Record Keepers

The estimate of the total annual cost burden to respondents or record keepers is based on the optional implementation of the HHLPSS software in state or local programs. The base software is provided at no cost to programs and NCEH provides technical support for implementation at no cost. Total capital and start-up cost component includes approximately $40,000 for computer hardware and software; however, state or local programs (e.g., health departments) may already have existing equipment that can be used. Total operation and maintenance and purchase of services for the maintenance of HHLPSS is approximately $5,000 per year; however, state or local programs (e.g., health departments) may already have existing computer software and servicing contracts in place that can be used for HHLPSS.

For the ABLES program, there are no capital/start-up or ongoing operation/maintenance costs associated with this information collection

A.14. Annualized Cost to the Federal Government

The combined annualized cost to the federal government for CBLS and ABLES is $7,780,833. The cost for each program is outlined below.

CBLS annualized estimated cost to the federal government is $7,730,833 and is based on the following:

Table A14.1. CBLS Annualized Costs

FY17 Cooperative Agreements for surveillance activities	$5,833,333
FTE Salaries for surveillance activities	$510,000
FTE Travel (to meet with CBLS stakeholders; site visits)	$50,000
Data Management, Health Communication, and Training Services	$687,500

(firm fixed price contracts)	
HHLPSS IT Support Services (firm fixed price contract)	$640,000
Contractor Travel (HHLPSS support provide to state & local agencies)	$10,000
Total Costs	**$7,730,833**

The annual FY17 cooperative agreement program budget for surveillance activities is estimated to be $5,833,333 per year. The annual federal personnel salary cost for surveillance activities is $510,000 based on 40 percent FTE of the total salary estimate of $1,275,000 for the following positions: Program Chief, Deputy Program Chief, 6 Project Officers, 1 IT Specialist, 2 Epidemiologists, 1 Communications Specialist.[15] Annual FTE travel cost is $50,000 based on the need for site visits, training, and meeting attendance. In FY17, the total overall operational and maintenance costs for HHLPSS is $650,000 for a firm, fixed-price contract (which includes $10,000 estimated travel to support state and local health departments). The contract provides for the services of five (5) IT specialists ranging from database administrator to direct user support with a focus primarily on management and operations of the system including along with a minimal amount of development and upgrades related to state/local health agency user requests. Other tasks include: data extraction, formatting, and validation to process data submitted to CDC. Additional contractual costs include $687,500 for data management, health communication, and training support services.

ABLES annualized estimated cost to the federal government is $50,000 and is based on the following:

Table A.14.2. ABLES Annualized Costs

FTE Salaries	$47,000.00
FTE Travel (to meet with ABLES stakeholders)	$3,000.00
Total Cost	**$50,000.00**

NIOSH staff working in the ABLES Program includes four part-time subject matter experts that total 0.5 FTE. Their duties are management and oversight of the multi-state ABLES surveillance system including: data management, data analysis, dissemination of findings, responding to public requests, and providing technical assistance to states. These employees spend approximately 1,044 hours per year working on the surveillance program. Using an estimated salary of $45 per hour, personnel costs will total $47,000 annually. One ABLES staff person also attends the annual national CSTE conference and makes occasional trips to attend other meetings with ABLES stakeholders. States are providing data to the ABLES Program on a

[15] Based on OPM Atlanta Locality Pay for Grade and Step 5 Salary Table at https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/pdf/2017/ATL.pdf.

voluntary basis and no direct funding to states is provided by NIOSH in support of the ABLES Program.

A.15. Explanation for Program Changes or Adjustments

This ICR represents a long-standing CDC collaboration between NCEH and NIOSH to collect, analyze, and disseminate blood lead surveillance data on children and occupationally-exposed adults in the U.S. (See **Attachment 10** – OMB Control Number History for Blood Lead Surveillance). NCEH and NIOSH are requesting a 3-year Paperwork Reduction Act (PRA) clearance that is a revision of a previously approved data collection [OMB Control Number: 0920-0931; expiration 05/31/2018].

CDC has been collecting CBLS data since 1994 [OMB Control Number: 0920-0337; expiration 04/30/2012]. In 2005, CDC requested and was approved for a revised ICR [OMB Control Number: 0920-0337] to include Adult Blood Lead Epidemiology and Surveillance (ABLES) data. In 2012, a new ICR [OMB Control Number: 0920-0931; expiration 05/31/2018] was approved to add "Healthy Homes" information to the National Lead Poisoning Prevention Surveillance System, including both CBLS and ABLES, and the previous ICR was discontinued.

However, despite approval to collect the "Healthy Homes" variables, the CDC Healthy Homes and Lead Poisoning Prevention Program was defunded by Congress in 2012 and this additional information collection was never realized at the national level. In addition, following on the Flint Water Crisis and subsequent new Congressional authorization and appropriations under the Water Infrastructure Improvements for the Nation (WIIN) Act of 2016, there is a renewed program focus on Lead Poisoning Prevention and Surveillance. Furthermore, the housing of blood lead data for children and occupationally-exposed adults is currently maintained in two separate data collection systems (in some states and at the national level), resulting in knowledge gaps on important topics such as the potential for "take-home" and maternal-child lead transmission resulting from workplace exposures.

Therefore, to correspond with the expiration date of the existing ICR, we are requesting a revision ICR for the 'Healthy Homes and Lead Poisoning Surveillance System (HHLPSS)' [OMB No. 0920-0931; expiration date: May 31, 2018].

<u>In summary, the changes to the original ICR are as follows</u>:

1. We request to <u>change the title</u> of the ICR from 'Healthy Homes and Lead Poisoning Surveillance System (HHLPSS)' to '**Blood Lead Surveillance System (BLSS)**' to more explicitly reflect the information collected by the NCEH Childhood Blood Lead Surveillance (CBLS) and the NIOSH Adult Blood Lead Epidemiology and Surveillance (ABLES) Systems.

2. We request to remove the NCEH 'healthy homes' variables from the existing HHLPSS ICR, as this data has never been collected at the national level, and to replace the HHLPSS variable list with the updated CBLS variable list .
3. We request to add specific ABLES data fields to the Healthy Homes and Lead Poisoning Software System (HHLPSS) that is used by many state and local agencies to collect and manage blood lead surveillance data.
4. We request to add 20 new CBLS respondents, over the 40 that were previously approved, due to the addition of newly-funded programs in FY17 and FY18.
5. We request to add 12 new ABLES respondents, over the 28 that were previously approved, due to the additional interest expressed by states for voluntary reporting.
6. We request to increase the annual time burden from 640 hours to 1,226 hours to account mainly for the increase in the number of respondents and for additional adjustments to the estimation. This is an increase of 586 annual burden hours.
7. We are working to integrate the information technology (IT) systems Childhood Blood Lead Surveillance (CBLS) and Adult Blood Lead Epidemiology and Surveillance (ABLES).

Therefore, this revised ICR will aim to: 1) refocus solely on blood lead surveillance data; 2) remove any confusion with previous plans to include "Healthy Homes" data as previously approved in 2012; and 3) integrate the collection of adult and child BLLs into one information technology system.

Blood lead data for children and occupationally-exposed adults are currently maintained in two separate systems, resulting in knowledge gaps on important topics such as potential for 'take-home and maternal-child lead exposures. We are proposing to combine childhood and adult blood lead surveillance at the national level and, thus, request a change the title of the ICR to 'Blood Lead Surveillance System.' Linking these two systems, CBLS and ABLES, ensures that CDC can identify and intervene for so-called 'take home' occupational exposures (Newman, et al. 2012) when workers bring lead-contaminated clothing or equipment home and expose family member including children and also begin to address the issue of maternal-child transmission of lead exposure (ACOG, 2012), in addition to childhood lead exposure from lead paint, contaminated water, soil, dust or consumer products.

From 1987-2013, NIOSH provided funding that resulted in the expansion of the ABLES program from 4 to 41 states. However, federal funding for state ABLES programs was discontinued in September 2013. Since 2016, ABLES has been working with NCEH CBLS program to incorporate adult blood lead information into the Healthy Home and Lead Poisoning Software System (HHLPSS). This ongoing initiative was encouraged by state partners to help them reduce personnel and time burden of data collection and data management. Currently no states

entering adult blood lead data are using HHLPSS because the software user-interface is in development.

Additionally, CBLS has added 14 new cooperative agreement recipients in FY17 and anticipates funding up to 12 additional awardees in FY18. Corresponding to the expiration of the existing ICR, NCEH proposes to modify the variable reporting requirements between the existing ICR and this revision ICR (**Attachment 6d**). In 2008-2010, the CDC CLPPP met with state and local programs and asked them to identify those data elements related to 'healthy homes' that could be collected under an expanded healthy homes program; however, that collection was never realized and, while the 'healthy homes' variables may reside in respondent systems for case management purposes, these variables were never added to the CBLS database. Beginning with this collection, the text format form name will be called "CBLS Variables" order to more accurately describe the NCEH-sponsored collection and revised to remove the 'healthy homes' variables that may reside in state and local agency systems but are not delivered to CBLS.

Modifications to the ABLES collection include the addition of 12 new respondents and a revised list of data elements (**Attachment 7c**). Over time, NIOSH has made changes to the ABLES standardized variables to update the ABLES case definition of an elevated BLL from ≥10 µg/dL to ≥5 µg/dL on the basis of evidence for adverse health outcomes among adults with BLLs as low as 5 µg/dL, which is consistent with CSTE recommendations (CSTE, 2015), and to provide additional variable definitions and details. Significant adjustments for this submission include the use of the revised case definition for elevated BLL and the addition of NAICS year and COC (Census Occupation Codes) year to capture the version of NAICS/COC used.

Also, for this submission, additional details relevant to burden hours are provided to improve clarity. The previous OMB submission estimated the combined burden hours and costs for ABLES and CBLS. In this current submission, burden hours and costs are provided separately for CBLS and ABLES and data collection method (individual "case" records and aggregate records).

This ICR will include the 34 existing and 14 newly funded in FY17, and up to 12 additional CBLS respondents for FY18 (annual time burden of 952 hours) and the 28 existing and an additional 12 new ABLES respondents (annual time burden of 280 hours). The total burden has changed from 640 hours to 1,232 hours due to the addition of more CBLS awardees in FY17 and FY18. Additionally NIOSH plans to include an additional 12 states during this upcoming reporting period, for a total of 40 states.

A.16. Plans for Tabulation and Publication and Project Time Schedule

CBLS Data Processing and Report Dissemination: Respondents are required to submit quarterly data to NCEH by the end of the subsequent quarter. Data submitted in text files to NCEH are

processed and maintained in the CBLS database. NCEH uses its processing software, CBLS Central, to perform data checks on recipient text files for required formatting. Text files are parsed into separate linkable data tables (e.g., Child, Address, Lab tests, Investigation) (**Attachments 6a & 6b**). Processing reports are generated and sent to recipients, to indicate how many records were properly parsed and entered into the CBLS database and how many records were not loaded with an explanation of the rejection. Data corrections are returned in the next quarterly report. Therefore, NCEH has a one to two quarter lag time for reporting results. CBLS Annual Reports are based on the calendar year.

Table A.16.1. CBLS Project Time Schedule

Activity	Time Schedule
Programs deliver FY1 Q1 data (Oct-Dec)	By end of FY1 Q2 (March 31)
CBLS Q1 Data Cleaning and Quality Control Processing Reports sent back to Programs	FY1 Q3 (April-June)
Programs deliver FY1 Q2 (Jan-Mar) data	By end of FY1 Q3 (June 30)
CBLS Q2 Data Cleaning and Quality Control Processing Reports sent to Programs	FY1 Q4 (July-September)
Programs deliver FY1 Q3 (Apr-Jun) data	By end of FY1 Q4 (September 30)
CBLS Q3 Data Cleaning and Quality Control Processing Reports sent to Programs	FY2 Q1 (October-December)
Programs deliver FY1 Q4 (Jul-Sep) data	By end of FY2 Q1 (December 31)
CBLS Q4 Data Cleaning and Quality Control Processing Reports sent to Programs	FY2 Q2 (January-March)
Annual Calendar Year Reports sent to Programs when Programs deliver FY2 Q1 (Oct-Dec) data	By end of FY2 Q2 (March 31)
Post Annual Data on Web and/or Publish Annual Calendar Year Report	By end of FY2 Q3 (June 30)

CBLS Publications and Results Dissemination: NCEH shares the de-identified aggregate/summary data without restriction to interested parties through its public website[16] and also through publications such as MMWR Surveillance Summary reports. CBLS datasets include some required variables with potentially personally identifiable information (PII) (e.g., age, race, sex, county of address) which may present privacy concerns due to small numbers for some of the variables. Therefore, small cell sizes (counts <5) will be redacted from all datasets or summary tables that are disseminated in any way. According to the 2015 HHLPSS Terms of Clearance (**Attachment 11**), dissemination of the aggregate data set and statistics generated from the aggregate data set will always be accompanied by the following caveats:

"These data were collected for program management purposes. The data are not generalizable at the national, state, or local level. Furthermore, because inclusion criteria vary across grantees, comparisons of aggregate statistics across programs can be misleading (i.e., state policies and practices for blood lead testing vary and local priorities drive decisions regarding which homes receive assessments for other housing hazards). However, descriptive statistics can be used to compare changes overtime in a given area when the method by which housing

[16] National and state aggregate data are provided at: https://www.cdc.gov/nceh/lead/data/

units are chosen for inclusion remains the same. With a thoughtful understanding of the approach used to include housing units in a given location, HHLPPS can be used to make associations between the number of individuals in a given area and a specific housing hazard or health condition and geographic descriptors such as poverty, age of housing, tenancy, and health conditions."

Table A.16.2. ABLES Project Time Schedule (Example recurring timeline)

ABLES Project Time Schedule	
Activity	**Time Schedule**
Request 2017 Data from States	February – March 2018
Receive 2017 Data from States	By June 30, 2018
Data Cleaning and Data Quality Control	March – July 2018
Work on Report Based on 2017 ABLES data	July – August 2018
Post and/or Publish Report	August – December 2018

ABLES publication and dissemination: Summary data from the ABLES program will be posted to the ABLES website.[17] In addition, aggregate ABLES data will also be made available on the NIOSH Worker Health Charts,[18] a data query and visualization tool. Data will be updated annually.

A.17. Reason(s) Display of OMB Expiration Date is Inappropriate

The display of the OMB expiration date is appropriate.

A.18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.

[17] ABLES website: https://www.cdc.gov/niosh/topics/ables/data.html
[18] Worker Health Charts: https://wwwn.cdc.gov/Niosh-whc/chart/ables-ab/exposure

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List of Attachments

Attachment 1a. NCEH Authorizing Legislation

Attachment 1b. NIOSH Authorizing Legislation

Attachment 2a. 60-day Federal Register Notice, CBLS-ABLES new ICR

Attachment 2b. 60-day Federal Register Notice, HHLPSS extension ICR

Attachment 3: NIOSH ABLES Inclusion History in NCEH ICRs

Attachment 4a. NCEH Notice of Funding Opportunity (NOFO) CDC-RFA-EH17-1701PPHF

Attachment 4b. NCEH Notice of Funding Opportunity (NOFO) CDC-RFA- EH14-1408PPHF

Attachment 5a. NCEH CBLS Program Summary & Accomplishments

Attachment 5b. NIOSH ABLES Program Summary & Accomplishments

Attachment 6a. HHLPSS Variables

Attachment 6b. CBLS Variables (ASCii Text Files)

Attachment 6c. CBLS Aggregate Records Form (Excel)

Attachment 6d. CBLS Differences in Variable Reporting Requirements

Attachment 7a. ABLES Case Records Form and Brief Narrative Report

Attachment 7a1. ABLES Standardized Variable Formats

Attachment 7b. ABLES Aggregate Records Form and Brief Narrative Report

Attachment 7c. ABLES Changes in Data Elements

Attachment 8a. NCEH CBLS Privacy Impact Assessment

Attachment 8b. NIOSH ABLES Privacy Impact Assessment

Attachment 9a. NCEH CBLS Research Determination

Attachment 9b. NIOSH ABLES Research Determination

Attachment 10. OMB Control Number History for Blood Lead Surveillance

Attachment 11. 2015 HHLPSS Notice of Action & Terms of Clearance